Submitter : Dr. Sandra Cupples **Date:** 03/23/2005

Organization : Washington Hospital Center

Category : Nurse

Issue Areas/Comments

Issues

HUMAN RESOURCES

RE: the proposed requirement for clinical transplant coordinators to be certified by the ABTC: Considering "grandfathering in" (a) all current clinical transplant coordinators or (b) those who have had at least 5 years experience at a transplant center that currently has Medicare approval.

Submitter : Dr. Arthur Eisenbrey **Date:** 03/23/2005

Organization : William Beaumont Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Section 482.96: The burden assessment vastly underestimates the time required to "develop, implement, and maintain a written comprehensive, data-driven QAPI program..." Having established a QAPI program for my hospital using the guidance and tools provided by the AABB, it took over 160 person-hours to develop and implement and 1.25 FTEs to maintain. If CMS intends for programs to establish an extremely superficial program, an eight hour investment will be a start.

Section 488.61: It is incredibly naive to assume that any transplant program would only invest 15 minutes to initiate a process that will determine whether or not the hospital transplant program will continue to exist. Composition and approval of the document (letter) may take days at most large medical institutions. CMS may not take this seriously, but the programs do and will.

Issues

HUMAN RESOURCES

Section 482.98, Standard: Clinical transplant coordinator: The proposal to require a single route to qualification is contrary to most existing policy and is in glaring contrast to the qualification requirements for social workers under Section 482.94: Standard: Social services. It is inappropriate for an agency of the Federal government to require participation in a single private organization as a prerequisite for participation in Federally-funded activities. This creates an non-competitive and monopolistic organization which can set fees at any level and prevent otherwise qualified individuals from offering the same services. Equivalent or alternative routes to qualification must be available so that Federal endorsement of a single private organization is not codified.

Submitter : Ms. Elaine Vuyosevich **Date: 03/24/2005**

Organization : Memorial Health University Medical Center

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

While I have not had the opportunity to read the whole report I did want to take this opportunity to voice my support for certification. If I am able to review the whole report before the close of the comment period I will also comment on the items above.
Thank you for giving me the opportunity to voice my opinion.

Issues

CRITERIA FOR CENTERS PERFORMING LIVING DONOR TRANSPLANTS

Having been involved with transplantation (medical professional) since 1969 I have seen and been an integral member of the medical community offering this service (primarily kidney but also heart transplantation) in various states during these past 25+ years. I have also been involved with the transplant coordinator's organization (NATCO) since 1980 as well as the credentialing group. I took the first test and have sat on both boards. I strongly urge and support the standard of having a CCTC (certified clinical transplant coordinator) as an integral member of this team. Before sitting the exam the individual must have experience in the field and continue in an on-going educational commitment to maintain the knowledge base needed to offer patients and family members the support and care needed to ensure quality care. I take pride in what I have done and will continue to support transplantation and it's professionals and feel strongly that certification is the best means of giving those who need transplantation the best possible chance at a better quality of life.

Submitter : **Mrs. Victoria Karp** **Date: 03/29/2005**

Organization : **California Pacific Medical Center**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sir or Madam:

Please accept this letter as notification of concurrence for the Centers for Medicare and Medicaid Services Proposed Rulemaking (CMS-3835-P), and in specific support of the proposed standard that a transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. And furthermore, this letter is in support that a qualified clinical transplant coordinator is an individual who is certified by the American Board of Transplant Coordinators (now legally incorporated as the American Board for Transplant Certification).

Quality patient care is vital to the transplant community, as is this mandatory requirement for professional certification of clinical transplant coordinators who perform direct patient care within the transplant community. The proposed standards will aid in ensuring the public's awareness of elevated safeguards to minimize medical errors associated with donation and transplant, and that the transplant industry has an objective methodology for assessing level of clinical transplant coordinator competency.

Sincerely yours,

Victoria Karp, RN, BS, CCTC
Liver Transplant Coordinator
California PAcific Medical Center

Submitter : **Ms. Beth DeLair** **Date: 04/08/2005**

Organization : **University of Wisconsin Hospital and Clinics**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3835-P-5-Attach-1.DOC

UWHealth
University of Wisconsin
Hospital and Clinics

Attachment #5
Electronically we can submit at http://www.cms.hhs.gov/regulations/ecomments

The Honorable Mike Leavitt
Department of Health and Human Services
Attention: CMS-3835-P
P. O. Box 8013
Baltimore, MD 21244-8013

Official Copy submitted to DHHS Website on June 13, 2005

Dear Secretary Leavitt,

The University of Wisconsin Hospitals and Clinics Authority (UWHCA) is pleased to have the opportunity to comment on the Secretary's proposed modifications to the "Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants." As a hospital providing transplant services since 1966, we appreciate the desire to ensure that all transplant centers provide an acceptable standard of care for transplant recipients. As such, UWHCA respectfully submits the following comments to the proposal.

Deleted:

Deleted: Medicare beneficiaries

§482.82 Condition of Participation: Data Submission and Outcome Requirements for Re-approval of Transplant Centers

"Proposed Outcome Measures"

UWHCA agrees with the proposal to require that a transplant center's one-year graft and patient survival be lower than expected as reported by the Scientific Registry of Transplant Recipients AND that transplant center must meet all three of the following thresholds: 1) the one-sided p-value is less than 0.05; 2) the number of observed events minus the expected events (O-E) is greater than three; 3) the number observed events divided by the number of expected events (O/E) is greater than 1.5. This proposal is reasonable and will eliminate surveys of transplant centers based on data that is not statistically significant.

§488.61 Special Procedures of Approval and Re-Approval of Organ Transplant Centers

UWHCA agrees with the proposal for re-approval that would require transplant centers to meet the data submission and outcomes requirements for re-approval proposed at §482.82. UWHCA concurs that it is a prudent use of resources to only survey centers applying for re-approval that do not meet the requirements as stated in §482.82.

Deleted: C. Outcome Measure Requirements for Initial Approval of Transplant Centers ¶
3. Proposed Outcome Measure Requirements for Heart, Kidney, Liver, and Lung Centers¶
b. Evaluation of Alternatives to the SRTR Methodology¶
¶
UWHCA agrees with the proposal to require that a transplant center's one year graft and patient survival be lower than expected as reported by the Scientific Registry of Transplant Recipients AND that transplant center must not meet all three of the following thresholds: 1) the one-sided p-value is less than 0.05; 2) the number of observed events minus the expected events (O-E) is greater than three; 3) the number observed events divided by the number of expected events (O/E) is greater than 1.5. This proposal is reasonable and will eliminate surveys of transplant centers based on data that is not statistically significant. We support the proposal as three and agree that Options 1 and 2 would create inefficiency by way of surveying programs based on random variation in data that is not significant. ¶

"Alternative Process to Re-Approve Transplant Centers"

The Proposed Process Requirements are consistent with other Joint Commission on Accreditation of Health Care Organizations and Organ Procurement and Transplantation Network (OPTN) standards and policies for which transplant centers are currently surveyed. Performing random surveys and/or surveying every center as part of re-approval is duplicative and would divert center resources away from patient care for additional survey preparation work. UWHC supports §488.61 as written.

Additionally, UWHCA is concerned with the alternative proposal to survey transplant centers based upon feedback from the OPTN. The proposed regulation as written at §488.61 is based on statistically significant data as opposed to "feedback" that may or may not be relevant to the competency of the transplant center to provide transplantation.

Sincerely,

Donna K. Sollenberger

Donna Sollenberger
President and CEO
University of Wisconsin
Hospitals & Clinics Authority
608/263-8025

Submitter : **Dr. Gerard M Turino** **Date: 04/11/2005**

Organization : **St Luke's-Roosevelt Hospital Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. Romano and Mr. Rogers: Thank you for your letter and your enclosure of a copy of the Federal Register regarding rereview of lung transplant centers every 3 years. This is to indicate that I am in favor of the proposal indicated under CMS-3835. I agree with the proposal of a 3-year reapproval period for lung transplant centers --- Gerard M Turino, MD

Issues

ALTERNATIVE PROCESS TO RE-APPROVE TRANSPLANT CENTERS

Dear Mr. Romano and Mr. Rogers: Thank you for your letter and your enclosure of a copy of the Federal Register regarding rereview of lung transplant centers every 3 years. This is to indicate that I am in favor of the proposal indicated under CMS-3835. I agree with the proposal of a 3-year reapproval period for lung transplant centers --- Gerard M Turino, MD

Submitter : Dr. Mary Hager **Date:** 04/22/2005

Organization : The American Dietetic Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues

PATIENT AND LIVING DONOR SELECTION

The American Dietetic Associatio agrees with CMS? position that transplant centers must make nutrition assessments and diet counseling services furnished by a qualified dietitian available to all transplant patients and living donors (? 482.94 Conditions of participation: Patient and living donor management) because of the potential adverse effects associated with food-drug interactions related to immuno-suppressant pharmacotherapy and other transplant surgery sequelae. The existing Medicare MNT benefit outlines regulatory language and requirements for providing MNT services for the ?.. medical condition of a beneficiary for 36 months after kidney transplant.?

As stated in the background of this proposed rule ?The Medicare statute contains specific authority for prescribing the health and safety requirements for facilities furnishing end-stage renal disease care to beneficiaries, including renal transplant centers, pursuant to section 1881(b)(a) of the Social Security Act. In keeping with the spirit of this law, ADA urges CMS to refer to Decision Memo for Medical Nutrition Therapy Benefit for Diabetes & ESRD (CAG-00097N)2 in defining a ?qualified dietitian? in the final rule.

Rationale: Effective January 1, 2002, Congress extended Medicare coverage for medical nutrition therapy (MNT) to beneficiaries with diabetes or a renal disease in section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA). MNT services are defined in statute as "nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional ... pursuant to a referral by a physician..."

In the final rule published on November 1, 2001 implementing this statutory provision (66 Fed Reg 55246), CMS established requirements regarding who may perform the service, the payment, and exclusions from coverage. CMS pays for MNT only provided by a registered dietitian or nutrition professional who meets the specified requirements under Medicare.

42 USC 1395x(vv) reads as follows: `(vv)(1) The term ?medical nutrition therapy services? means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional (as defined in paragraph (2)) pursuant to a referral by a physician (as defined in subsection (r)(1)).

Furthermore, CMS defines renal disease for the purpose of Medicare coverage as: "Renal disease means chronic renal insufficiency, end-stage renal disease when dialysis is not received, or the medical condition of a beneficiary for 36 months after kidney transplant."

Therefore, ADA believes that CMS, through the agency?s 2001 regulatory language for Medicare MNT, has already established and defined the minimum qualifications for `qualified dietitians? to include dietetic registration as specified in standards established by the Commission of Dietetic Registration, an independent body of the ADA. Medicare enrollment of registered dietitians/nutritionists as a new provider group started in December of 2001 and Medicare contractors started payment Medicare claims for MNT for diabetes and renal disease for services provided on or after January 1, 2002, the statutory effective date.

ADA is supporting legislation that authorizes CMS to extend MNT coverage based on scientific evidence without additional statutory changes required for each new condition covered, relying instead on the National Coverage Determination process. In addition, specific authorities could allow CMS to expand the MNT coverage to additional kinds of organ transplants such as those specified in the proposed rule for patients taking prescription drugs that have an adverse nutritional side effect or nutrition-related concerns.

Please emailv(202-775-8277) Dr. Mary Hager, Senior Manager, Regulatory Affairs, for further information. See attached letter

Submitter : **Date: 05/03/2005**

Organization : **Saint Barnabas Health Care System**

Category : **Hospital**

Issue Areas/Comments

Issues

OUTCOME MEASURE REQUIREMENTS

4. Re: Outcomes Measures

There needs to be some mechanism for taking into account that a Transplant Center is actively involved in research trials, perhaps new immunosuppression protocols, as this may impact a Center?s graft survival and so would need to be factored in as a risk adjustment.

PATIENTS AND LIVING DONOR RIGHTS

1. Re: Living Donor Advocacy

As there are so many variations in program size and methods of functioning, each Transplant Center should be able to define its process and structure for donor advocacy utilizing its existing trained professionals in a way that promotes an unbiased advocacy for living donors. For example, the clinical social worker may be defined as the ?donor advocate?, consistent with the existing social work role/ function. Another example of program policy might be that the evaluating physician/social worker could be separate for the donor and for the recipient.

It is difficult to imagine how a Transplant Center would find someone, outside of its realm and professional expertise, who would have the knowledge, capacity and effectiveness to function as a Donor Advocate as intended by the statute. Furthermore, if the Center contracts with such an individual, then the contractual arrangement in itself could be viewed as a conflict. Another option would be to have UNOS be the gatekeeper by setting up an Ombudsman type component (similar to nursing home models) which would be a resource available to all donors nationwide.

PATIENT AND LIVING DONOR SELECTION

2. Re: Written Long-Term Care Plan

This needs more definition. The question is why does a Renal Transplant Center need to establish a written long term care plan when they are really not managing the patient?s care. It would be more appropriate to require that a Transplant Center request a copy of the patient?s long-term care plan from the dialysis unit to be part of its records.

HUMAN RESOURCES

3. Re: Data Reporting

There is tremendous pressure placed on the infrastructure of the Transplant Center to meet the enormous data reporting requirements within the imposed timelines. There needs to be some clear guidelines for data coordinator functions (qualifications/volume to data coordinator ratio etc) as well as a defined means for reimbursement for data reporting costs. (i.e. can 100% of salary be allocated to Kidney Acquisition even though much of the data reporting is post transplant?)

Submitter : Dr. Ruud Krom **Date:** 05/09/2005

Organization : Mayo Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Finally. It seems to me that the approval process by CMS for reimbursement for Medicare patients in need of an organ transplant is a doubling of the approval process by UNOS and the DOT. In order to save money it should be wise to streamline he approval process and select one organization to perform this effort. Programs / centers , that are in the !? problem!? zone, either by outcome measures, or changes or lack of infrastructure can be flagged and brought to the attention of CMS or vice versa to the DOT / UNOS.
As the methodology developed by the SRTR and the Center Specific Data is reported to UNOS / DOT as well as CMS, it seems logical to bring the review process in one organization.

Issues

CRITERIA FOR CENTERS PERFORMING PEDIATRIC TRANSPLANTS

CENTERS PERFORMING PEDIATRIC TRANSPLANTS: I disagree with the statement that!? Because the occasional adult patients , being transplanted at the pediatric centers and the relatively few pediatric transplants in general, we are not requiring a minimum number of transplants (adults or pediatric) for pediatric centers.!? I strongly suggest to put a volume (and outcome) measure as a requirement for reimbursement. This opens the door for a small program with minimal resources to do pediatric and adult transplants !?unchecked!? and below the radar screen of quality control. In addition, I believe that there is a !?typo!? in this paragraph: !? we propose that in centers where patients are predominantly (!U 50 percent) adult patients ????? ?C shouldn!?t this be !Y 50 percent?

PATIENT AND LIVING DONOR SELECTION

With regard to !?living donor!? selection, I would like to see a independent physician, not directly involved in the transplant process of the intended recipient , as the !?ombudsman!? in the selection and decision making process for the donor.
Page 6163: PATIENTS AND LIVING DONORS. The mentioning of OPO activity in the text related to Living Donors is confusing. OP!?s have nothing to do with living donor selection etc.

OUTCOME MEASURE REQUIREMENTS

I like the statistical approach based on SRTR methodology. However, it seems that the volume requirement has now changed from 12 transplant in one year to 9 transplants in 2,5 years. I believe that this is unacceptable low. No program/center with only 9 transplants in 2,5 years (3.6 transplant/year) can be considered a legitimate transplant program. With this volume, clinical expertise cannot be build up and maintained. Already 12 transplants /year seems awkwardly low, but can at least be considered OK as a start of a potentially OK program, assuming growth. Nine transplant in 2,5 years does not qualify a program in a !?start-up!? phase. Despite the fact that the SRTR is able to flag these programs statistically, it totally ignores that transplant expertise and infrastructure cannot be considered present. Of the alternative options I consider option 1 better than option 2.
I completely disagree with the 1 month post transplant outcome data for !?special circumstances!? like moving a !?whole team!? from one hospital to another. This is a scary slippery slope. Never moves a !?whole!? team, but only a subset. Moreover, the hospital might lack the !?transplant infrastructure!?, which consequences cannot be demonstrated within one month results. Too often this !?loophole!? is used to expand an existing program into a neighboring hospital. The recent proposal by Memorial Hospital of Miamy is a typical example. The team is not moving, some members of the team are nominated the program directors, to cover the move. However no additional staff nor tested infrastructure is present. If a real move of a program occurs from one to anther hospital, I suggest initial approval after a minimum time of 6 months and a minimum volume of 9 transplants. If the results are clearly above par, respective reimbursement might be considered. Obviously, I disagree with the Proposed outcome measure requirements for initial approval a shown on page 6157.The text following the 3th bullet (If the center!?s observed 1-year patient and graft survival is lower than its expected etc) softens the consequences of the text following the 2th bullet even further. I suggest that the program will not be approved if only of the 3 thresholds are crossed. If CMS is really concerned about the quality of care for Medicare patients, approval of inexperienced, below par programs should be avoided (at all cost!!!!).

PATIENTS AND LIVING DONOR RIGHTS

The recommendation by ACOT for living donor standards and disclosure seems to be appropriate.

HUMAN RESOURCES

I support the proposal for a designated director for each organ program / center.

Submitter : Dr. Pedro Vergne-Marini **Date:** 05/13/2005

Organization : Methodist Dallas Transplant Institute

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Issues

CRITERIA FOR CENTERS PERFORMING LIVING DONOR TRANSPLANTS

see attachment

PATIENT AND LIVING DONOR SELECTION

see attachement

CRITERIA FOR CENTERS PERFORMING PEDIATRIC TRANSPLANTS

See attachment

PROVIDER VS. SUPPLIER STATUS for APPEALING PURPOSE

see attachment

ALTERNATIVE PROCESS TO RE-APPROVE TRANSPLANT CENTERS

see attachment

PATIENTS AND LIVING DONOR RIGHTS

see attachement

HUMAN RESOURCES

see attachment

OUTCOME MEASURE REQUIREMENTS

see attachment

CMS-3835-P-10-Attach-1.DOC

CMS-3835-P-10-Attach-2.DOC

Methodist
DALLAS MEDICAL CENTER

P.O. Box 655999
Dallas, Texas 75265-5999

1441 N. Beckley Ave.
Dallas, Texas 75203

Attachment#10

List of Comments on Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants.

Special Procedures of Approval and Re-approval of Organ Transplant Centers (488.68)

- The OPTN or UNOS should be the only entity with the responsibility to monitor and coordinate the procedures for approval or re-approval of transplant centers.
- A simplified application process and a site visit should only occur for new programs and existing programs not meeting outcome and data submission requirements. Programs in existence who meet outcome and data submission requirements should not be surveyed except what is currently scheduled by UNOS.
- Random sampling is unnecessary when compliance has always been met.
- CMS does not have a remediation period for centers that are not performing according to standards. If you do not meet these standards you are dropped as a transplant center. UNOS has a remediation period.
- Centers are to be surveyed once every three years. What is the cost of completing these surveys on an annual basic?
- The degree and amount of data being submitted by the transplant field is unlike any other field of medicine. No one is mandated to supply so much information that consumes so much staff time and effort. The data requirements form UNOS grow regularly and the staff needed to collect and enter this data in UNET is growing while we are being constrained with fiscal outs. The data is now overwhelmingly post transplant and by current CMS rules governing the Organ Acquisition Account, cannot be changed to that fund. Hospitals are being forced to choose between providing staff to take care of patients vs. completing data forms. CMS needs to either increase funding for the transplant procedure, allow us to charge this expense to the OAC or extend the time limit for data completion beyond 90 days.

Notification to CMS (482.74)

- No comments currently.

Pediatric Transplants (482.76)

[If you choose to comment to CMS on this section please include the caption "CENTERS PERFORMING PEDIATRIC TRANSPLANTS" at the beginning of your comments.]

- UNOS requirements for a Pediatric transplant center should be the standard.
- Volume requirements are not applicable to pediatric programs

Data Submission and Outcome Requirements (482.80/482.82)

[If you choose to comment to CMS on this section please include the caption "OUTCOME MEASURE REQUIREMENTS" at the beginning of your comments.]

- Transplant Center performance should be measured on its outcomes.
- Volume is logical to include in determining outcomes as this has been demonstrated to impact outcomes.
- The proposed methodology of using 1 year patient and graft actual versus expected and the three criteria to measure outcome would not be difficult for centers to achieve. Comparing a centers performance based on its own population of transplant recipients and organ donors is the only reasonable comparison.
- Using one-month data to assess a new programs performance is reasonable after one year of performing transplants. However, 90 days would be more appropriate to evaluate the surgical complications. Requiring one year data to be submitted when available is reasonable.
- The criteria for defining experienced teams should be the criteria for UNOS approval. The proposed description of 1 year of prior experience to quality for applying with one month data is too vague and not an appropriate measure.
- OPTN's outcome data was never designed as a Medicare test
- There is no provision for remediation or corrective action.
- There is no risk adjustment built into the models for several important factors.
- The definition of expanded is constantly changing.
- Patients might be denied transplant in order to meet outcome requirements.
- Expanded criteria organs might not be used.

- CMS should consult with OPTN and deny re-approval unless transplant center fails remediation.

- UNOS has established requirements for data submission, outcome measures, and process requirements. Renal transplant centers currently collect and submit transplant data to the OPTN using six different forms. Amending the current data submission to the OPTN, a body that includes scientist, would be less cumbersome and less costly than creating a new system.

- SRTR and Center-Specific Reports
  Improvements in SRTR center-specific reports should be implemented. Experts on the OPTN committees and the Secretary's Advisory Committee on Organ Transplantation (ACOT) currently review these data. Significant time and monies will be necessary for a new body, not necessarily comprised of persons with backgrounds in medicine or transplantation, to develop the expertise to truly improve the care of kidney transplant recipients.

Patient and Living Donor Selection (482.90)

[If you choose to comment to CMS on this section please include the caption "PATIENT AND LIVING DONOR SELECTION" at the beginning of your comments.]

- Selection criteria should follow the standards adopted by the majority of experts in the field of transplantation and should serve only as guidelines.
- Making criteria anything but guidelines will place undue legal risk when trying to instead apply appropriate Medical judgement.

- Protocols for living donors should be developed within the principles of medical Ethics.

- Written selection criteria is unnecessary and redundant, OPTN has transplant care and management guidelines.

- Confidentiality (LD's suitability be documented in the recipients chart)

- LD selection must be consistent with general medical ethics (vague, what is that?)

- Centers must exhaust all available therapies before considering transplant option, however the Patient Selection Criteria is constantly changing. Where do you set the upper and lower margins?

- There are cases where patients are turned down although all criteria are met. Often patients barely meet each selection criteria and when a decision is made after reviewing all factors, the patient is turned down. This happens due to combinations of shortcomings too varied to be codified. A certain "grey-area" must be maintained in this decision-making process.

- CMS wants the Transplant Centers to be involved in the pre-transplant patient care. Sometimes this is not possible due to distance the patient lives from the center and problems with maintaining contact. The social and nutritional aspects of care are already being addressed more effectively by patients' local physicians, dialysis units and medical facilities.

- Disclosure of alternatives to selection criteria should not be defined. It again poses legal areas of risk and can interfere with medical judgement.

- Criteria for evaluation of potential recipients are codified as clinical practice guidelines developed by the Patient Care and Education committee of the American Society of Transplantation (AST). These have been presented as *guidelines*, rather than strict criteria, because subtleties exist in the practice of medicine. To document exacting and specific selection criteria ignores the fact that transplant selection criteria have evolved the first transplant and continue to evolve. Evidence-based medicine is not available for all aspects of the pre-transplant evaluation, e.g., urology, hematology-oncology.

- Living donor selection
  Criteria for evaluation of potential living donors were also developed by the Ad Hoc Clinical Practice Guidelines Subcommittee of the Patient Care and Education Committee of the AST.

- Requiring a psychological evaluation for all potential living donors will delay the time and increase the cost for this process. It is difficult to envision coercion in the classic example of a parent donating a kidney to a child.

Organ Recovery and Receipt (482.92)

- These are the guidelines already being surveyed by UNOS.

- The OPO is responsible for collecting data during organ recovery, some of this data may not be available at the time of transplantation (response to "surgeon is responsible for ensuring medical suitability of donor organs.")

- Recipients not identified at recovery, all data may not be known before acceptance or leaving for recovery (suggest: organ recovery teams review data before accepting organ)

- OPOs determine protocols; more than one recovering team may have different protocols.

- How can a surgeon be made accountable for an organ when surgeons have to rely on information from the OPO which may not be accurate?

- Validation of data should be part of a protocol but sets up areas for unnecessary legal risk as detailed in proposal.

Patient and Living Donor Management (482.94)

- Patient data is required to be up to date for organ allocation.
- The OPTN or UNOS should be the only entity setting these guidelines as it impacts the allocation system.
- UNOS has requirements for personnel. Each program should have personnel to meet the needs of the population. Social services and nutrition should be available. There are no other disciplines and health care expertise that are also critical to a quality program and listing these few is greatly understating the need. UNOS requirements are higher standards.
- Many patients are not managed pre or post transplant by the transplant center.
- Yearly notification to patients on wait list cannot always be done.
- The waitlist management should not have detail defined in the COPs. This is another area of legal risk that should not be part of this type of regulation.
- Will CMS audit a kidney transplant program for both deceased donor and living donor recipients if it fails to meet criteria in only deceased donor recipients or living donor recipients?
- Medicare should have a national coverage policy on living donation in extra renal organs before it determines any standards in this area.
  - UNOS should develop the standards for this area and enforce the standards as part of current 3-year survey.
- A living donor registry exists and greater emphasis on follow-up of livings donors has been mandated in the scientific literature and at scientific meetings. The cost of follow-up care of living donor will not be insignificant. To date, neither Medicare nor any private insurance company has made monies available for assessment of renal function, blood pressure, or proteinuria in this population.

Quality Assessment and Performance Improvement (482.96)

- Adverse events that occur that are not related to transplant but related to end stage organ disease should not be addressed in a transplant QA process. This needs to be clarified for exclusion.
- Transplant does not have dedicated resources to focus on QA for the entire transplant process. Additional personnel will need to be added to meet this need.

- If the evaluation system that relies on SRTR's risk-adjusted data is UNOS, why not recommend that UNOS track additional information? While UNOS and proposed CMS are similar but equal in their assessment of outcome, an unnecessary and redundant expense of money and time will necessary to devote to record preparation and submission. These resources of time and monies will take away from time devoted to patient care. These new regulations may delay transplantation of innumerable patients with staff time devoted away from pre-transplant evaluation, post-transplant education and thereby increase morbidity and mortality of CKD.

Human Resources (482.98)

- The OPTN guidelines for program personnel requirements should set the industry standard. This can be monitored by UNOS.

- Definitions are vague.

- Is only one qualified clinical transplant coordinator required per program (deceased donor or living donor) or more than one required?

- Centers must have certified surgeon/physician as director. If a physician completes an approved ASTS fellowship he/she is certified for all transplant programs even if the fellowship was in a hospital that only performs kidney transplants. There is no general test at the end of the fellowship (maybe there should be).

Organ Procurement (482.100)

- Transplant centers should notify the OPTN or UNOS if an OPO agreement has been terminated.

Patient and Living Donor Rights (482.102)

[If you choose to comment to CMS on this section please include the caption "PATIENTS' AND LIVING DONORS' RIGHTS" at the beginning of your comments.]

- Guidelines should be developed by experts in the transplant community and published by OPTN as a resource and used for UNOS to monitor. ACOT is an appropriate standard.

- OPTN guidelines should be used for notification of unavailability of surgeon.

- Informed consent process: This is not realistic. A patient may be on waitlist for 3 to 5 years. The informed consent process is gone through at the time of evaluation. The patient probably does

not remember most of this by the time they are transplanted and there is usually not enough time to go through it prior to surgery (very extensive).

- Through CMS, dialysis centers already have written patient management policies and patient care planning for pre-transplant. In addition, transplant programs have documentation for patients provided by physicians, nurses, transplant coordinators, social workers, and dietitians.

- Living Donor management policies can be viewed and amended by UNOS.

- Transplant waitlist management as recommended by the 2002 Clinical Practice Committee of the AST, would be better incorporated under scientific auspices (UNOS) rather than under nonscientific auspices.

- Review of policies determining medical suitability for transplantation can be incorporated in UNOS regulations and site visits.

Additional Requirements of Kidney Transplant Centers (482.104)

- Kidney transplant should remain associated with the ESRD network for comprehensive ESRD oversight.

- If JCAHO or AOA began monitoring kidney transplant programs, the cost of running a transplant program would increase.

Alternative Process to Re-Approve Transplant Centers

[If you choose to comment to CMS on this section please include the caption "ALTERNATIVE PROCESS TO RE-APPROVE TRANSPLANT CENTERS" at the beginning of your comments.]

- Limiting a transplant center's approval to 3 years would vastly increase the number of administrative staff to maintain a transplant program. The documentation from multiple disciplines and multiple professionals may well impact to the number of patients approved for transplantation and the number of transplants performed.

- The proposals put forth will create a revolving door of paperwork and bureaucratic morass. Furthermore, UNOS fulfills the role of performing site visits to transplant centers.

General comments

- Any survey is a duplication of efforts as the United Network for Organ Sharing (UNOS) already surveys the transplant centers every 3 years for most aspects included in the document.

- Any additional survey requirements should be delegated to the OPTN

- UNOS approval for participation meets the personnel requirements for transplant centers and should be the standard.

- The centers that would fall out as not meeting requirements (based on data submission, outcomes) are already easily identified (approximately 10%). It would be more appropriate and less costly to address the centers already not meeting criteria than requiring the 90% of centers who already meet or exceed the criteria to spend the time documenting what is already known.

- The centers not meeting the criteria should have to complete the documentation for COP and the other centers should be grandfathered in as meeting the criteria

- Kidney programs should not be considered for the same initial approval criteria. Because kidney transplants are the majority of either Medicare primary or Medicare secondary as the payer, it would be difficult to transplant 9 non-Medicare patients. The current approval process is for one patient to be transplanted and then conduct an onsite survey to validate requirements are met. This should not change.

- The elimination of Medicare immunosuppressant coverage for the life of a transplant when performed at a non-Medicare approved facility is detrimental to the long term outcomes of transplant patients and is a disincentive for new programs to be initiated.This restriction should be eliminated before any extension is added to the timeframe to qualify as and approved transplant center. Even if a patient is transplanted at a non-Medicare facility, they should be allowed Medicare immunosuppressant coverage.

- Will the 3 yearly data submission(s) to CMS be performed on line?

Submitter : **Mrs. Renia Harris-Hellams** **Date: 05/23/2005**

Organization : **Robert Wood Johnson University Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3835-P-11-Attach-1.DOC

CMS-3835-P-11-Attach-2.DOC

ATTACHMENT #11
ROBERT WOOD JOHNSON UNIVERSITY HOSPITAL MEDICARE PROVIDER # 310038

Comments on the Medicare Program:
42 CFR Parts 405, 482 and 488 Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants; Proposed Rule

PROPOSED GENERAL REQUIREMENTS FOR TRANSPLANT CENTERS

Condition of Participation: Pediatric Transplant (Proposed Section 482.76)

"Centers Performing Pediatric Transplant" - We agree that centers that wish to perform pediatric transplants must meet hospital CoP's for the pediatric patient. However we disagree that separate Medicare approval is necessary for pediatric transplant. The numbers of pediatric patients with Medicare coverage is insignificant and few and does not justify the costs in labor time to seek separate approval.

PROPOSED TRANSPLANT CENTER PROCESS REQUIREMENTS

Condition of Participation: Patient and Living Donor Selection (Proposed Section 482.90)

"Patient and Living Donor Selection" - We have no objection to making patient selection criteria available to patients either routinely or upon request. In fact we believe that providing such information to patients will aid in the patient education process about transplantation.

Condition of Participation: Patient and Living Donor Management (Proposed Section 482.94)

1. We disagree with the proposal that the kidney transplant physician is to manage the patient's care during every stage of transplantation. Heart and liver transplants involve patients who are critically ill and are often in the hospital awaiting their transplant. Therefore, under such circumstances it might be reasonable to expect that the transplant physicians will have care plans and will manage the pre-transplant care. In contrast to this, kidney and pancreas transplant patients generally wait on lists for years. During this wait time kidney and pancreas transplant patients are being cared for by their referring physicians. It is not possible for the transplant center to manage the kidney and pancreas transplant patient's care prior to transplant and to have short and long-term care plans during this period of time. To do this the transplant centers would have to run dialysis centers and manage the patient's anemia, calcium, phosphate, diabetes, hypertension and such in the pre-transplant period. Were the

transplant center to assume such responsibilities from the time of referral for evaluation, no nephrologist would ever again refer a patient to a transplant center. The responsibility of caring for these patients pre-transplant is in the hands of the referring physician.

2. It is proposed that patients should not be selected for a transplant unless other therapies have been tried that would be expected to have similar survival rates to that of a transplant. We do not agree that patient survival rate should be the only criterion by which to consider a patient for a transplant. A pancreas transplant may prevent a patient from going blind, improve their gastroparesis and neuropathy and prevent diabetic nephropathy from developing in the transplanted kidney. Even if a pancreas after kidney transplant does not prolong life beyond that of a live-donor kidney transplant it does offer some distinct advantages.

3. Annual notification to patients of their waitlist status is not always possible especially in kidney/pancreas transplant centers where patients are on the waitlist for years and during this time are managed by their primary nephrologist/physician. We would propose that waitlist management be clinically driven and that the transplant center as part of the patient management criteria identify 'high risk' patients who need to be seen annually. We would recommend that the transplant patient need a specific "Patient Bill of Rights and Responsibilities" in which the patient acknowledges in writing that he or she has the responsibility to keep the transplant center informed of his/her whereabouts.

Condition of Participation: Quality Assessment and Performance and Performance Improvement (QAPI) (Proposed Section 482.96) - Most hospitals, if not all, have policies that address adverse events including reporting requirements and procedures for investigation and follow up. If such a policy exists as an organization wide document will the transplant center be required to develop a separate policy?

Condition of Participation: Human Resources (Proposed Section 482.98)

"Human Resources" - UNOS has personnel requirements for transplant centers that should be the gold standard. Personnel needs vary and transplant centers need flexibility to meet the needs of their patients.

Condition of Participation: Patient and Living Donors' Rights (Proposed Section 482.102)

"Patients' and Living Donors' Rights"

1. It is proposed that the consent form for live donors contain a statement that donation may adversely affect future eligibility for health, disability, and life insurance. We

disagree with including such statement to the consent form. Live donor kidney transplants are the most successful type of kidney transplants. The stated goal of these proposed changes is to increase the number of successful transplants. We believe the proposed American Board of Transplant Coordinators' recommended consent form will not achieve increased donations. We do agree that transplant centers need to have an informed consent process for both donor and recipient to discuss the risks, benefits and alternatives to transplant.

2. We do not believe that adding a requirement for transplant center to provide the service of an independent donor advocate (or advocacy team) will add much value. We are unclear about how such an "independent" advocate will be provided if the transplant center has to pay the salary of such an individual. If the advocate is a volunteer this approach could also be problematic for the center.

SPECIAL PROCEDURES FOR APPROVAL AND RE-APPROVAL OF TRANSPLANT CENTERS

"Effect of New CoPs for Transplant Centers on Centers That Are Currently Medicare –Approved"

1. State designated agencies and the OPTN currently have the authority and responsibility for survey of CoPs and transplant centers. Additional surveys would be duplicative, costly for the transplant center and possibly cause confusion for the transplant center and their patients.

2. Transplant centers that have Medicare designation when these proposed CoPs are approved should not be required to re-apply. Re-approval every three years should be based on an evaluation of the data for patient and graft survival and the survey processes via the State designated agency and the OPTN that are already in place.

Submitter : **Mrs. Barbara Griffin** **Date: 05/30/2005**

Organization : **Gambro Health Care**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

This is in support of the national CNSW comments on legislation effecting criteria for Social Workers within the transplant setting. Specifically , to specify the professional Social Worker position as a part of a multidisciplinary evaluation process of all transplant candidates and to mandate that the Social Worker is an MSW and meets the licensing requirements of their state. As the field of Nephrology Social Worker has continued to evolve along with the transplant process, the specific skills that are possessed by trained Social Workers is a vital part of this process.

Submitter : **Ms. Lara Tushla** **Date: 05/31/2005**

Organization : **Rush University Transplant Program**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3835-P-13-Attach-1.DOC

Attachment#13
5726 S. Stony Island #3
Chicago IL 60637
773-955-7141
ltushla@rush.edu
May 30, 2005

Comments on Proposed Transplant Regulations file code CMS–3835–P

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-3835-P
PO Box 8013
Baltimore MD 21244-8013

Dear CMMS:

For almost 7 years, I have been a Social Worker in a large, urban Transplant Center. Prior to that, I was a Social Worker in an outpatient dialysis unit. I have been looking forward to seeing new Conditions of Coverage (COC) for Chronic Kidney Disease facilities.

I fully support the Response for the Council of Nephrology Social Workers. I have been a member of this fine organization since 1993. Additionally, I would like to address some of the individual sections in this letter.

Issue: Patient and Living Donor Selection (Section 482.90):

RECIPIENT:
I strongly support the requirement that every prospective transplant candidate receive a comprehensive evaluation by a Qualified Social Worker (MSW and licensed in the state, if applicable) prior to placement on the list. Despite the fact that the vast majority of pre-transplant patients seen in our clinic have been on dialysis for some time and have had a psychosocial assessment by the Social Worker in the dialysis unit, the issues related to transplantation are unique. I have worked with people who did very well on dialysis, but were not successful in managing a kidney transplant.

The phrase "psychosocial evaluation" should be clarified to explicitly state that the transplant candidacy evaluation should be conducted by a Qualified Social Worker. People with Chronic Kidney Disease (CKD) have multiple psychosocial stressors that can negatively impact on a person's ability

to care for a transplanted kidney. A Qualified Social Worker assesses the multiple factors that impact of successful outcomes and makes recommendations to maximize a person's transplant candidacy and positive outcomes.

DONOR:
Under the same Section 482.90, I also strongly support mandating thorough assessments for potential living donors. **I also believe that the phrase "psychosocial assessment" should explicitly state that the evaluation should be completed by a Qualified Social Worker.** As the cadaveric donor pool remains fairly stagnant, candidates are strongly encouraged to attempt to identify potential living donors. With the increase in living, unrelated kidney donors, "advertising" for donors, and websites attempting to match potential donors with potential recipients... it is crucial that potential donors receive thorough assessments. The responsibility of the Transplant Center is to ensure the safety of the donor, physically, mentally, socially, and financially.

SEPARATE TEAMS:
To maintain a truly independent assessment of a potential donor, every attempt should be made to have two separate teams to assess the recipient and donor. When the same team is assessing both, the possibility of putting the recipient's need for an organ over potential risks to the donor may exist.

Issue: 482.94 Condition of participation: Patient and living donor management

I support the Standard regarding Social services, which states the transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which practicing, which includes having completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education.

I think the statement "Has served for at least 2 years as a social worker, one year of which was in a transplantation program, and has established a consultative relationship with a social worker" is misleading and would allow centers to use non-qualified staff persons to perform such a crucial evaluation and intervention.

Transplant patients should have the same access to Qualified Social Workers as do people on dialysis. Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The complex multi-factorial issues, which impact on the success of a transplant, require a comprehensive approach to assessment and intervention. Master's prepared Social Workers

are unique within the mental health field in their holistic approach to working with clients.

Issue: 482.98 Condition of participation: Human resources

I believe the following statement "The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology" should be changed to use the phrase **social work.** The correct reference to the profession is social work. There is no degree in "social services." The phrase minimizes the efforts of social workers in every profession and leaves open for interpretation who performs these services.

Thank you for your attention to this response. If there is any other information I can offer, please feel free to contact me.

Sincerely,

Lara Tushla, LCSW
Transplant Social Worker

Submitter : Ms. Betty Crandall **Date:** 05/31/2005

Organization : Sentara Norfolk General Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

For comprehensive comments to the proposed Conditions of Participation, please see the attached Word document.

Issues

CRITERIA FOR CENTERS PERFORMING PEDIATRIC TRANSPLANTS

> For adult transplant programs who also perform a few pediatric transplants in older adolescents (ages 14-18), requiring Medicare approval as both an adult and a pediatric center is unnecessarily burdensome. We would propose that, if an adult program only performs a small number of transplants in older adolescents, approval as an adult program should be sufficient to allow reimbursement from Medicare for those few and infrequent pediatric transplants.

OUTCOME MEASURE REQUIREMENTS

> Using the SRTR center-specific reports as the foundation for CMS's outcome evaluation system is efficient and cost effective and avoids duplicate reporting of data, already a sizeable burden for transplant hospitals.
> As part of this proposed revision of the Conditions of Participation for Transplant Hospitals, CMS must address the fact that data submission requirements are not currently allowable costs on the Medicare Cost Report. The data submission requirements imposed by the OPTN and now proposed by CMS are immense and costly for transplant hospitals. CMS must, at least, designate these as allowable costs under the Cost Report.
> Using both patient and graft survival as measures of a center's performance is appropriate. Both are important. Using a statistically valid system such as that used by SRTR is appropriate. The SRTR analysis also incorporates risk adjustment which is critical in assessing center performance.
> Data about the impact of volume on outcomes in transplantation are controversial and conflicting. Therefore, eliminating volume as a separate standard and integrating it into the outcomes assessment is a positive change in the Medicare Conditions of Participation.
> The proposal to allow new centers expedited approval if the key members of the team had come from a Medicare approved transplant center where they had performed transplants for at least one year is a positive change. However, we would suggest that CMS should consider requiring 3 month data rather than one month data. Complications of the surgery and immediate post operative management may not be evident in the first month post transplant, but would be reflected in the first 90 days. It would seem that 3 months would be a reasonable period for evaluation of outcomes and would not place an undue financial burden on a facility. Requiring a formal re-evaluation once one year data are available will be critical to assure that the team is still performing at acceptable levels to assure the quality of patient care. CMS should also consider using the current OPTN definition for an experienced team.
> Proposing no outcome measures requirements for heart/lung, intestinal, and pancreas transplant programs at this time is appropriate. Such measures should be included if and when SRTR is able to establish a risk adjusted model as exists for other types of organ transplants. Requiring heart/lung transplants to be performed in a transplant hospital approved for both heart and lung transplants is appropriate as is the requirement for intestinal transplant centers to be in transplant hospitals approved for liver transplant and that for pancreas transplant centers to be located in transplant hospitals approved for kidney transplant.

PATIENTS AND LIVING DONOR RIGHTS

> We concur that assuring that rights of patients and living donors are protected is critical. As part of the informed consent process, it is the responsibility of the physician/surgeon obtaining informed consent to provide the patient all of the information he/she would require to make a truly informed decision. That is the standard that should be in place, not specific requirements of the information about which the patient must be informed. Being overly prescriptive about the content of an informed consent is not the standard in medicine and should not be established as part of the regulatory framework here. The legal standard is that the patient is provided all of the information in a manner he/she can understand to allow him/her to make an informed decision. Secondly, it must be remembered that informed consent is a process, not a document. Courts have upheld that a particular form is not required. What is required is what was stated above: the patient/alternative decision maker is given sufficient information on which to make an informed decision about treatment or another course of action.
> CMS should not mandate the naming of a specific donor advocate for a living donor. Centers should be held to the requirement that there is a process in place to assure that the living donor is assessed in a manner that independently evaluates the risks and benefits of their serving as a living donor and that such a process must be separate from the process to evaluate a potential recipient's needs.
> The OPTN already has requirements in place addressing the process to be followed if a center is unable to provide transplant services to listed patients. There is no need for CMS to have this as a separate requirement.

HUMAN RESOURCES

> The requirements for a primary transplant surgeon and primary transplant physician are in line with the requirements of the OPTN and are reasonable.
> The requirement for a qualified transplant coordinator is reasonable if the requirement is that there be one qualified coordinator as defined (certified by ABTC) on site for the center to provide overall direction in the areas outlined. It is not reasonable to expect that all transplant coordinators employed by a transplant hospital are certified. Some may not meet the eligibility requirements to even sit for the certification exam. Clarification is requested as to this requirement.
> The OPTN has requirements for personnel. Those for CMS should be consistent. Conflict between the two sets of criteria will be difficult to manage.

PATIENT AND LIVING DONOR SELECTION

> The requirement for centers to have written patient selection criteria which are regularly reviewed and updated is very reasonable. Nearly all centers have this in place currently and this would not be burdensome to implement. Requiring documentation in the patient!|s record of which specific requirements were used is

unnecessary and burdensome. If a center is required to have written criteria in place and is able to demonstrate what those criteria were at any time, the information may be cross-referenced without implementing a system of documentation that is unreasonable and burdensome and which serves no purpose.
> It is not reasonable to require, as a condition for approval, that a transplant center consider or employ all other appropriate medical and surgical therapies that might be expected to yield short and long term survival comparable to transplantation prior to selecting a patient as a transplant candidate. Those therapies are continually evolving and it is a physician's medical judgement what therapies are most appropriate for a patient under his care. There is no consistent and objective way to measure such a requirement.
> Requiring all transplant candidates to undergo a psychosocial evaluation is appropriate and reasonable. It should remain up to the transplant center who performs that assessment as long as the persons doing so are qualified and perform the functions defined by UNOS in its policies.
> UNOS already has systems in place for determining a candidate's ABO blood type and assuring that the correct type is accurately entered into the electronic UNet system. Referencing those requirements is preferable to establishing new requirements.
> The requirement for centers performing living donor transplants to have written selection criteria for living donors which are regularly reviewed and updated is very reasonable. Nearly all centers have this in place currently and this would not be burdensome to implement. Documentation about the transplant team!|s decision about the suitability of a particular living donor candidate in that individual's chart is reasonable. It is not reasonable to document that in a potential recipient's chart. That is a breach of the potential donor's confidentiality.
> Living donors must have an adequate medical and psychosocial evaluation prior to a determination of suitability. There must also be a process for informed consent and documentation in the record that the living donor has provided informed consent for the procedure.

CMS-3835-P-14-Attach-1.DOC

Attachment#14
Proposed General Requirements for Transplant Centers

Condition of Participation: OPTN Membership (Proposed section 482.72)

This proposed Condition of Participation is reasonable and is in concert with established requirements.

Condition of Participation: Notification to CMS (Proposed section 482.74)

Requiring a center to notify CMS regarding any significant changes that would affect its approval as a transplant center is reasonable. Once the criteria for approval of a transplant center are finalized, clear criteria for notification of CMS must be defined and published.

Condition of Participation: Pediatric Transplants (Proposed section 482.76)

CENTERS PERFORMING PEDIATRIC TRANSPLANTS

- For adult transplant programs who also perform a few pediatric transplants in older adolescents (ages 14-18), requiring Medicare approval as both an adult and a pediatric center is unnecessarily burdensome. We would propose that, if an adult program only performs a small number of transplants in older adolescents, approval as an adult program should be sufficient to allow reimbursement from Medicare for those few and infrequent pediatric transplants.

Proposed Transplant Center Data Submission and Outcome Requirements

Condition of Participation: Data Submission and Outcome Measure Requirements for Initial Approval of Transplant Centers (Proposed section 482.80)

OUTCOME MEASURE REQUIREMENTS

- Using the SRTR center-specific reports as the foundation for CMS's outcome evaluation system is efficient and cost effective and avoids duplicate reporting of data, already a sizeable burden for transplant hospitals.
- As part of this proposed revision of the Conditions of Participation for Transplant Hospitals, CMS must address the fact that data submission requirements are not currently allowable costs on the Medicare Cost Report. The data submission requirements imposed by the OPTN and now proposed by CMS are immense and costly for transplant hospitals. CMS must, at least, designate these as allowable costs under the Cost Report.
- Using both patient and graft survival as measures of a center's performance is appropriate. Both are important. Using a statistically valid system such as that used by SRTR is appropriate. The SRTR analysis also incorporates risk adjustment which is critical in assessing center performance.
- Data about the impact of volume on outcomes in transplantation are controversial and conflicting. Therefore, eliminating volume as a separate standard and integrating it into the outcomes assessment is a positive change in the Medicare Conditions of Participation.
- The proposal to allow new centers expedited approval if the key members of the team had come from a Medicare approved transplant center where they had performed transplants for at least one year is a positive change. However, we would suggest that CMS should consider requiring 3 month data rather than one month data. Complications of the surgery and immediate post operative management may

not be evident in the first month post transplant, but would be reflected in the first 90 days. It would seem that 3 months would be a reasonable period for evaluation of outcomes and would not place an undue financial burden on a facility. Requiring a formal re-evaluation once one year data are available will be critical to assure that the team is still performing at acceptable levels to assure the quality of patient care. CMS should also consider using the current OPTN definition for an experienced team.

- Proposing no outcome measures requirements for heart/lung, intestinal, and pancreas transplant programs at this time is appropriate. Such measures should be included if and when SRTR is able to establish a risk adjusted model as exists for other types of organ transplants. Requiring heart/lung transplants to be performed in a transplant hospital approved for both heart and lung transplants is appropriate as is the requirement for intestinal transplant centers to be in transplant hospitals approved for liver transplant and that for pancreas transplant centers to be located in transplant hospitals approved for kidney transplant.

Condition of Participation: Data Submission and Outcome Measure Requiremtns for Re-approval of Transplant Centers (Proposed 482.82)

OUTCOME MEASURE REQUIREMENTS

- Using the same outcome measure for re-approval of transplant centers is reasonable. Employing the same methods which are scientifically based and statistically valid is appropriate.

Proposed Transplant Center Process Requirements

Condition of Participation: Patient and Living Donor Selection (Proposed Section 482.90)

PATIENT AND LIVING DONOR SELECTION

- The requirement for centers to have written patient selection criteria which are regularly reviewed and updated is very reasonable. Nearly all centers have this in place currently and this would not be burdensome to implement. Requiring documentation in the patient's record of which specific requirements were used is unnecessary and burdensome. If a center is required to have written criteria in place and is able to demonstrate what those criteria were at any time, the information may be cross-referenced without implementing a system of documentation that is unreasonable and burdensome and which serves no purpose.
- It is not reasonable to require, as a condition for approval, that a transplant center consider or employ all other appropriate medical and surgical therapies that might be expected to yield short and long term survival comparable to transplantation prior to selecting a patient as a transplant candidate. Those therapies are continually evolving and it is a physician's medical judgement what therapies are most appropriate for a patient under his care. There is no consistent and objective way to measure such a requirement.
- Requiring all transplant candidates to undergo a psychosocial evaluation is appropriate and reasonable. It should remain up to the transplant center who performs that assessment as long as the persons doing so are qualified and perform the functions defined by UNOS in its policies.
- UNOS already has systems in place for determining a candidate's ABO blood type and assuring that the correct type is accurately entered into the electronic UNet

system. Referencing those requirements is preferable to establishing new requirements.

- The requirement for centers performing living donor transplants to have written selection criteria for living donors which are regularly reviewed and updated is very reasonable. Nearly all centers have this in place currently and this would not be burdensome to implement. Documentation about the transplant team's decision about the suitability of a particular living donor candidate in that individual's chart is reasonable. It is not reasonable to document that in a potential recipient's chart. That is a breach of the potential donor's confidentiality.
- Living donors must have an adequate medical and psychosocial evaluation prior to a determination of suitability. There must also be a process for informed consent and documentation in the record that the living donor has provided informed consent for the procedure.

Condition of Participation: Organ Recover and Receipt (Proposed Section 482.92)

Most of the proposed requirements in this section are established requirements of the OPTN and, because all Medicare approved centers would have to be members of the OPTN and abide by its policies, these do not need to be duplicated here in the Conditions of Participation. If they need to be restated here, they should be the exact same requirements of the OPTN so that there is not confusion or conflict between the requirements.

The recipient may not be known at the time of organ recovery for some (abdominal) organs. Thus, a requirement that the recovery team review and compare the recipient and donor data before recovery takes place cannot be met.

Condition of Participation: Patient and Living Donor Management (Proposed Section 482.94)

It is not feasible for the transplant center to be responsible for the management of chronically ill patients who are awaiting transplantation or to have in place the documentation of involvement of a multidisciplinary team. These patients, particularly renal transplant candidates, are managed by referring physicians and care teams and may not be at the transplant center except for periodic evaluation of their status. The responsibility for their ongoing management during the period (which may be months or years) of waiting for a transplant resides with the physician and care team primarily responsible for their care management, not with the transplant center.

We are glad to see that CMS does not propose a formal annual evaluation process for all patients listed on a center's UNOS list. The requirements that a transplant center reassess patients frequently enough and in a manner to assure the accuracy and currency of patient information and that the patient remains a suitable candidate for transplant is sufficient and reasonable.

It is reasonable to require that there be documentation that each patient evaluated for transplant has been notified of their acceptance as a candidate, their non-acceptance, or the inability of the team to determine their candidacy. However, requiring documentation of annual notification of all listed patients about their transplant status is unreasonable and would be incredibly burdensome for transplant hospitals. The current requirement for the OPTN is that patients are notified when their status changes. That is a reasonable approach to assuring that patients are informed about changes in their status.

UNOS has established requirements for the psychosocial functions/services which must be available in a transplant center. We would suggest that CMS adopt those requirements rather than the more prescriptive requirements proposed. What is important is that the patient receives the necessary services by a qualified person, not the specific qualifications of the provider of the services. The same mode should be used for nutritional services. CMS should define the types of services (education and counseling) that is required, not the qualifications of the person providing those services.

Condition of Participation: Quality Assessment and Performance Improvement (QAPI) (Proposed Section 482.96)

Requiring a defined process for QAPI related to transplant is reasonable. Most centers would have a process in place due to the existing requirements for hospitals. However, CMS should not become prescriptive about the elements of the plan, the processes monitored, or the data collected and reviewed.

Adverse events in transplant should be reviewed as part of the overall hospital's adverse events/sentinel events process. A separate policy and process should not be required. The hospital is already required under JCAHO standards to have such a process. Having a separate requirement for transplant is duplicative and resource intensive.

Condition of Participation: Human Resources (Proposed Section 482.98)

HUMAN RESOURCES

- The requirements for a primary transplant surgeon and primary transplant physician are in line with the requirements of the OPTN and are reasonable.
- The requirement for a qualified transplant coordinator is reasonable if the requirement is that there be one qualified coordinator as defined (certified by ABTC) on site for the center to provide overall direction in the areas outlined. It is not reasonable to expect that all transplant coordinators employed by a transplant hospital are certified. Some may not meet the eligibility requirements to even sit for the certification exam. Clarification is requested as to this requirement.
- The OPTN has requirements for personnel. Those for CMS should be consistent. Conflict between the two sets of criteria will be difficult to manage.

Condition of Participation: Organ Procurement (Proposed Section 482.100)

This Condition of Participation is reasonable.

Condition of Participation: Patients' and Living Donors' Rights (Proposed Section 482.102)

PATIENTS' AND LIVING DONORS' RIGHTS

- We concur that assuring that rights of patients and living donors are protected is critical. As part of the informed consent process, it is the responsibility of the physician/surgeon obtaining informed consent to provide the patient all of the information he/she would require to make a truly informed decision. That is the standard that should be in place, not specific requirements of the information about which the patient must be informed. Being overly prescriptive about the content of an informed consent is not the standard in medicine and should not be established as part of the regulatory framework here. The legal standard is that the patient is provided all of the information in a manner he/she can understand to allow him/her to make an informed decision. Secondly, it must be remembered that informed consent is a process, not a document. Courts have upheld that a particular form is not required. What is required is what was stated above: the patient/alternative decision maker is given sufficient information on which to make an informed decision about treatment or another course of action.
- CMS should not mandate the naming of a specific donor advocate for a living donor. Centers should be held to the requirement that there is a process in place to assure that the living donor is assessed in a manner that independently evaluates the risks and benefits of their serving as a living donor and that such a process must be separate from the process to evaluate a potential recipient's needs.

- The OPTN already has requirements in place addressing the process to be followed if a center is unable to provide transplant services to listed patients. There is no need for CMS to have this as a separate requirement.

Condition of Participation: Additional Requirements for Kidney Transplant Centers (Proposed Section 482.104)

These requirements are reasonable.

Special Procedures for Approval and Re-Approval of Transplant Centers

G. Effect of New CoPs for Transplant Centers on Centers That Are Currently Medicare-approved

The proposal to treat all currently Medicare approved transplant centers as new centers and require a reapplication process and an on site survey is bureaucratic, unreasonably costly for CMS and the centers, and unnecessary. By reviewing the data submission and outcomes information, centers who do not meet these requirements can be easily identified. Those should be the centers for whom a survey is conducted. The remaining centers, those in compliance with the data submission and outcomes requirements, should be grandfathered and remain Medicare approved.

Submitter : Mrs. Suzanne Miller **Date:** 05/31/2005

Organization : The Nebraska Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

There is no other field of medicine that is more scrutinized and more visible than transplantation. Data requirements increase regularly for both transplant recipients and living donors. Factor in the increase in living donors and the 90 day submission goal and fiscal constraints. It has become a difficult situation to manage and monitor.

Issues

CRITERIA FOR CENTERS PERFORMING LIVING DONOR TRANSPLANTS

UNOS is requesting one year follow up data on living donors however not all transplant programs are following their donors past the post-op visit because of clinic and staff constraints.

HUMAN RESOURCES

Is only one certified clinical transplant coordinator required (as indicated in the audio-conference)? If only one is required, would it be expected that they be in a leadership role? Will there be an expectation in the future that all would need to be certified?

PATIENT AND LIVING DONOR SELECTION

Patient confidentiality has become a very delicate issue with regards to living donor transplants. This must be protected for both the donor and the recipient. Documentation on either chart about the other must be carefully considered for current and future ramifications.

Recipient selection criteria should be considered ?guidelines? to selection of candidates. For the renal population, a patient?s candidacy must be weighed against their risk of remaining on dialysis and their quality of life.

I believe that selection criteria should be available only on request.
Wait list management is difficult in terms of staff requirements, distance of the patient from the transplant center, and fragile nature of our patient population.
While I agree that the transplant center should actively re-evaluated all of the patients on the list on at least a yearly basis to maintain their candidacy, the re-evaluation alone will not necessarily assure that the patient is in the best health possible at transplant. A key component to maintaining candidacy has to include the specialists and/or primary care physicians communication to the transplant center with pertinent changes in their patient?s health.
For our kidney program alone, the re-evaluation of the waitlisted patients would double our evaluations and clinic appointments per year. Many patients are listed for several years before transplanted and may have several evaluations during that period of time.

It?s hard to imagine a process that would provide a reliable administrative system to track patient status and provide accurate updated patient data on demand for effective wait list management when patients are located across the state or out of state.

Regarding notification to the patient of decision after Selection Committee ? is a phone call adequate in most cases? (A letter only when listed or denied?)

An annual update to the patients listed would only be a snapshot in time. A patient could put on hold and reactivated several times a year.

OUTCOME MEASURE REQUIREMENTS

How the patients are followed post-transplant and who follows them will affect outcome results. There is financial impact to transplant programs that follow their patients more closely in terms of staff requirements.

Aggressive transplant programs may be penalized by the use of expanded and expedited criteria donors and/or involvement in research studies that could affect their outcome data. Transplant programs may deny patients access to transplant in order to meet outcome requirements.

There is no other field of medicine that is more scrutinized and more visible than transplantation. Data requirements increase regularly for both transplant recipients and living donors. Factor in the increase in living donors and the 90 day submission goal and fiscal constraints. It has become a difficult situation to manage and monitor.

PATIENTS AND LIVING DONOR RIGHTS

Written? informed consent is reference several times throughout the proposed Conditions of Participation. I have several questions regarding this:
Patients are given lengthy detailed information during the transplant evaluation. How often would this need to be repeated prior to obtaining consent at time of transplant?
How would recipient informed consent be documented to meet requirements?
What would be the requirements of ?documented? informed consent for living donors?
Do donors need their own written consent form at time of transplant?

Submitter : **Mrs. Anne Murphy** **Date: 06/01/2005**

Organization : **University of Michigan Transplant Center**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Issues

HUMAN RESOURCES

This paragraph stipulates that each Transplant Center must employ an ABTC certified Transplant Coordinator. Given the definition of a Transplant Center in paragraph 482.70, we are interpreting this to mean that each organ program must have a certified coordinator. At the University of Michigan we have consolidated our kidney, pancreas, liver and lung transplant programs into one Transplant Center. Due to economies of scale we have a long established division of labor where our pre-transplant support activities are divided between non-clinical pre-transplant coordinators and pre-transplant nurses. This new requirement would effectively exclude our highly trained and experienced non-clinical transplant coordinators from qualification. We would like this requirement to be modified to 'grandfather? in current Transplant Coordinators who may not be ABTC certified. Additionally, we would like the requirement to be modified to clarify that for multi-disciplinary Transplant Centers (covering multiple organ programs), that only one ABTC certified coordinator is required for the center, vs. a requirement that we have a minimum of four certified coordinators for four organ programs.

PATIENTS AND LIVING DONOR RIGHTS

Patient and Living Donor Rights ? Subparagraph (7) requires that Transplant Centers inform transplant candidates in writing that, ?Organ donor risk factors could affect the success of the graft or the health of the patient, including but not limited to the donor?s history, condition or age of organs used, or the patient?s potential risk of contracting human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected organ.? Please clarify the intent of this paragraph. If it is the intent that the written informed consent includes the above statement, then we find this to be acceptable. If the intent is that each transplant candidate receives a detailed written explanation of the specific risk factors associated with their particular donor organ, then we request that this requirement be modified. Complying with this requirement in a comprehensive and consistent manner, by providing details on the potential variability in outcomes for each specific organ will be onerous and logistically improbable given the time constraints on the process of donor identification, organ recovery and transplant.

Submitter : **Dr. Constance Glasby** **Date: 06/02/2005**

Organization : **University Medical Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues

CRITERIA FOR CENTERS PERFORMING LIVING DONOR TRANSPLANTS

482.92 ORGAN RECOVERY AND RECEIPT
The ABO policy is thoroughly covered by the OPTN policies and has been implemented through the OPTN listing systems.

482.94 PATIENT AND LIVING DONOR MANAGEMENT-WAITLIST MANAGMENT
Requirement for patient notification each year of their status on the list. This is a redundant requirement. OPTN policy already requires notification at the time of listing and when a status change is made. Patients on heart and liver lists are followed closely, seen frequently and know their listing status. Dialysis centers know if a patient is listed by having to get blood samples for PRA levels as requested by the listing transplant center.

OUTCOME MEASURE REQUIREMENTS

482.82 TRANSPLANT CENTER DATA SUBMISSION AND OUTCOME REQUIREMENT FOR RE-APPROVAL OF TRANSPLANT CENTERS
Programs who are already Medicare certified should be recertified if they meet the first two requirements, i.e. data submission and outcomes. The third requirement, processes, can be reviewed when the OPTN comes for their scheduled review. If they do not meet the first two requirements then more close review is warranted.

Submitter : Dr. Constance Glasby **Date: 06/02/2005**

Organization : University Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

As a transplant administrator I appreciate the development of these regulations. It has collated all of the regulations for transplant programs into one document. It is my opinion that in many areas there has been extra burden placed on non-renal transplant programs as a carry over from the ESRD regulations. Please consider the following objections, concerns and requests for clarification I have regarding this notice.

482.80 TRANSPLANT CENTER DATA SUBMISSION AND OUTCOME REQUIREMENT

Experience of centers to startup: Surgeon taking experience with him to a new program. Why would that qualify a center? There are many more factors that make a transplant center and it is not totally dependent on the surgeon or physician. There needs to be a clearer definition of team memebers and what it will take to start up a new program. I also question the validity of requiring only 9 transplants in the 2.5 year period and the validity of allowing a program to gain Medicare certification with only 1 months work of data. Studies have shown a surgical specialty needs to perform a certain number of procedures per year in order to maintain proficiency and quality outcomes. (Reference: An Assessment of CABG Surgery among Arizona Medicare Beneficiaries, 1994-1997 by Carter and Murcko for the Health Services Advisory Group)

482.90 PATIENT AND LIVING DONOR SELECTION

Donor advocacy team for living donors: This would cause a hardship on small programs. Programs are dedicated to protecting the welfare of donors and if there is any problem or question the donor is deferred.

Patient selection: It is not clear how a center is supposed to meet the requirement that before a patient is selected (except for kidney) the transplant center must employ or consider all other appropriate medical and surgical therapies. Does this have to be stated in the patient's medical record and proven by what means? When a patient is placed on the waitlist, the center must document in the patient's medical record the patient selection criteria used. What is expected to show this?

482.96 QUALITY ASSURRANCE AND PERFORMANCE IMPROVEMENT

I believe the monitors suggested will not affect or improve patient outcomes. Protocols for adverse events are already a JCAHO requirement and hospital sentinel event policies and reporting mechanisms are in place. Programs need to develop individualized quality improvement programs directed at their own problem areas.

482.98 HUMAN RESOURCES

CMS shold not designate a certifying agency for transplant coordinators. There are several agencies that certify nurses and CMS should not specify one over the others.

Dietician requirement. Compliance with this requirement will be met when the patient is an inpatient for the actual transplant. If this is a requirement for the pre-transplant stage, during the evaluation, it will be onerous for the extra renal programs. Patients are cared for by their cardiologist or hepatologist. The transplant program sees the patient for their evaluation, makes recommendations and returns the patient to their primary physician. Recommendations as to weight control or loss to meet selection critera will be addressed in communication to the primary physician and the patient A dietary consult at this stage will be expensive and will fractionate the patient's care. Cardiac diets, etc., should be under the direction and monitoring of the primary physician.

482.102 PATIENTS' AND LIVING DONOR RIGHTS

Patient Selection Criteria. The requirement that patients should be specifically educated to the selection criteria is very perscriptive. Each patient is unique and selection critera need to be applied individually to each. Selection criteria are never absolute. The selection committee decision can be very subjective;it is not black and white. This requriement could be detrimental to patients, make them give up hope or loose confidence.

COST TO ADMINISTER

I think the the cost estimate is low.

Submitter : Dr. Constance Glasby **Date:** 06/02/2005

Organization : University Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

ALTERNATIVE PROCESS TO RE-APPROVE TRANSPLANT CENTERS
I agree it would be appropriate for CMS to base decisions about the need to conduct individual transplant center surveys on information provided by the OPTN.

The OPTN should be the entity to survey transplant programs as it is already reviewing programs every three years for compliance with listing policies. The OPTN has the data and sets the standards for practice.

Programs who are already Medicare certified should be recertified if they meet the first two requirements, i.e. data submission and outcomes. The third requirement, processes, can be reviewed when the OPTN comes for their scheduled review.
482.102 PATIENTS AND LIVING DONORS RIGHTS
Requirement of informing patients of certain risk factors:
How will each patient be alerted to specific donor risk factors in the case of a deceased donor it is a matter of hours before the transplant that the specific information about the donor is known. The patient is being brought in for transplant, taken to the OR, and prepped. The transplant coordinator is often not present. This is not the time to be discussing specific donor risk factors. This requirement will be difficult to implement.
COST TO ADMINISTER/IMPLEMENT
If the OPTN is not used to administer and implement this regulation it will require the establishment of a complete new monitoring entity familiar with transplant programs and transplant policies. I believe the $300,000 additional expense quote is not an accurate estimation.

Submitter : Mr. Ian Jamieson **Date:** 06/02/2005

Organization : Shands Transplant Cntr at University of Floridia

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-3835-P-20-Attach-1.DOC

Attachment #20
List of Comments on Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants.

Special Procedures of Approval and Re-approval of Organ Transplant Centers (488.68)

- The OPTN or UNOS should be the only entity with the responsibility to monitor and coordinate the procedures for approval or re-approval of transplant centers.
- A simplified application process and a site visit should only occur for new programs and existing programs not meeting outcome and data submission requirements. Programs in existence who meet outcome and data submission requirements should not be surveyed except what is currently scheduled by UNOS.
- Random sampling is unnecessary when compliance has always been met.
- CMS does not have a remediation period for centers that are not performing according to standards. If you do not meet these standards you are dropped as a transplant center. UNOS has a remediation period.
- Centers are to be surveyed once every three years. What is the cost of completing these surveys on an annual basis?
- The degree and amount of data being submitted by the transplant field is unlike any other field of medicine. No one is mandated to supply so much information that consumes so much staff time and effort. The data requirements from UNOS grow regularly and the staff needed to collect and enter this data in UNET is growing while we are being constrained with fiscal cuts. The data is now overwhelmingly post transplant and by current CMS rules governing the Organ Acquisition Account, cannot be charged to that fund. Hospitals are being forced to choose between providing staff to take care of patients vs. completing data forms. CMS needs to either increase funding for the transplant procedure, allow us to charge this expense to the OAC or extend the time limit for data completion beyond 90 days.

Notification to CMS (482.74)

- No comments.

Pediatric Transplants (482.76)

- UNOS requirements for a Pediatric transplant center should be the standard.
- Volume requirements are not applicable to pediatric programs

Data Submission and Outcome Requirements (482.80/482.82)

- Volume is logical to include in determining outcomes as this has been demonstrated to impact outcomes.

- The proposed methodology of using 1 year patient and graft actual versus expected and the three criteria to measure outcome would not be difficult for centers to achieve. Comparing a centers performance based on its own population of transplant recipients and organ donors is the only reasonable comparison.
- Using one-month data to assess a new programs performance is reasonable after one year of performing transplants. However, 90 days would be more appropriate to evaluate the surgical complications. Requiring one-year data to be submitted when available is reasonable.
- The criteria for defining experienced teams should be the criteria for UNOS approval. The proposed description of 1 year of prior experience to quality for applying with one month data is too vague and not an appropriate measure.
- There is no provision for remediation or corrective action.
- There is no risk adjustment built into the models for several important factors.
- The definition of "expanded" is constantly changing.
- Patients might be denied transplant in order to met outcome requirements.
- Expanded criteria organs might not be used as transplant organs.
- CMS should consult with OPTN and deny re-approval unless transplant center fails remediation.
- There is tremendous pressure placed on the infrastructure of the Transplant Center to meet the enormous data reporting requirements within the imposed timelines. There needs to be some clear guidelines for data coordinator functions (qualifications/volume to data coordinator ratio etc) as well as a defined means for reimbursement for data reporting costs. (i.e. can 100% of salary be allocated to Kidney Acquisition even though much of the data reporting is post transplant?)
- There needs to be some mechanism for taking into account that a Transplant Center is actively involved in research trials, perhaps new immunosuppression protocols, as this may impact a Center's graft survival and so would need to be factored in as a risk adjustment.
- Experience of centers to startup: Surgeon taking experience with him to a new program. Why would that qualify a center? There are many more factors that make a transplant center and it is not totally dependent on the surgeon or physician. There needs to be a clearer definition of team members and what it will take to start up a new program. I also question the validity of requiring only 9 transplants in the 2.5 year period and the validity of allowing a program to gain Medicare certification with only 1 months worth of data. Studies have shown a surgical specialty needs to perform a certain number of procedures per year in order to maintain proficiency and quality outcomes. (Reference-An Assessment of CABG Surgery Among Arizona Medicare Beneficiaries, 1994-1997 by Carter and Murcko for the Health Services Advisory Group)

- Programs who are already Medicare certified should be recertified if they meet the first two requirements, i.e. data submission and outcomes. The third requirement, processes, can be reviewed when UNOS comes for their scheduled review. If they do not meet the first two requirements then more close review is warranted.

Patient and Living Donor Selection (482.90)

- Selection criteria should follow the standards adopted by the majority of experts in the field of transplantation and should serve only as guidelines.
- Protocols for living donors should be developed within the principles of medical ethics.
- Written selection criteria is unnecessary and redundant, OPTN has transplant care and management guidelines.
- Confidentiality concerns (LD's suitability be documented in the recipients chart).
- LD selection must be consistent with general medical ethics (this is a vague statement).
- Centers must exhaust all available therapies before considering transplant option, however the Patient Selection Criteria is constantly changing. Where do you set the upper and lower margins?
- There are cases where patients are turned down although all criteria are met. Often patients barely meet each selection criteria and when a decision is made after reviewing all factors, the patient is turned down. This happens due to combinations of shortcomings too varied to be codified. A certain "grey-area" must be maintained in this decision-making process.
- CMS wants the Transplant Center to be involved in the pre-transplant patient care. Sometimes this is not possible due to distance the patient lives from the center and problems with maintaining contact. The social and nutritional aspects of care are already being addressed more effectively by patients' local physicians, dialysis units, and medical facilities.
- The question is why does a Renal Transplant Center need to establish a written long term care plan when they are really not managing the patient's care. It would be more appropriate to require that a Transplant Center request a copy of the patient's long-term care plan from the dialysis unit to be part of its records.
- Donor advocacy team for living donors: This would cause a hardship on small programs. Programs are dedicated to protecting the welfare of donors and if there is any problem or question the donor is deferred.
- Patient selection. It is not clear how a center is supposed to meet the requirement that before a patient is selected (except for kidney) the transplant center must employ or consider all other appropriate medical and surgical therapies. Question: Does this have to be stated in the patient's medical record and proven by what means?

- When a patient is placed on the waitlist, the center must document in the patient medical record the patient selection criteria used. Question: What is expected to show this?

Organ Recovery and Receipt (482.92)

- These are the guidelines already being surveyed by UNOS.
- The OPO is responsible for collecting data during organ recovery, some of this data may not be available at the time of transplantation (response to "surgeon is responsible for ensuring medical suitability of donor organs.")
- Recipients are not identified at recovery, all data may not be known before acceptance or leaving for recovery (suggest: organ recovery teams review data before accepting organ)
- OPOs determine protocols; more than one recovering team may have different protocols.
- How can a surgeon be made accountable for an organ when surgeons have to rely on information from the OPO which may not be accurate?
- The ABO policy is thoroughly covered by the OPTN policies and has been implemented through the OPTN listing systems.

Patient and Living Donor Management (482.94)

- Patient data is required to be up to date for organ allocation.
- The OPTN or UNOS should be the only entity setting these guidelines as it impacts the allocation system.
- UNOS has requirements for personnel. Each program should have personnel to meet the needs of the population. Social services and nutrition should be available. There are no other disciplines and health care expertise that are also critical to a quality program and listing these few is greatly understating the need. UNOS requirements are higher standards.
- Many patients are not managed pre or post transplant by the transplant center.
- Yearly notification to patients on wait list cannot always be done.
- Will CMS audit a kidney transplant program for both deceased donor and living donor recipients if it fails to meet criteria in only deceased donor recipients or living donor recipients?
- Medicare should have a national coverage policy on living donation in extra renal organs before it determines any standards in this area.
  - UNOS should develop the standards for this area and enforce the standards as part of current 3-year survey.

- Requirement for patient notification each year of their status on the list. This is a redundant requirement. OPTN policy already requires notification at the time of listing and when a status change is made. Patients on heart and liver lists are followed closely, seen frequently and know their listing status. Dialysis centers know if a patient is listed by having to get blood samples for PRA levels as requested by the listing transplant center.

Quality Assessment and Performance Improvement (482.96)

- Adverse events that occur that are not related to transplant but related to end stage organ disease should not be addressed in a transplant QA process. This needs to be clarified for exclusion.
- Transplant does not have dedicated resources to focus on QA for the entire transplant process. Additional personnel will need to be added to meet this need.
- The monitors suggested will not affect or improve patient outcomes. Protocols for adverse events are already a JCAHO requirement and hospital sentinel event policies and reporting mechanisms are in place. Programs need to develop individualized quality improvement programs directed at their own problem areas.

Human Resources (482.98)

- The OPTN guidelines for program personnel requirements should set the industry standard. This can be monitored by UNOS.
- Definitions are vague.
- Is only one qualified clinical transplant coordinator required per program (deceased donor or living donor) or more than one required?
- Centers must have certified surgeon/physician as director. If a physician completes an approved ASTS fellowship he/she is certified for all transplant programs even if the fellowship was in a hospital that only performs kidney transplants. There is no general test at the end of the fellowship (maybe there should be).
- CMS should not designate a certifying agency for transplant coordinators. There are several agencies that certify nurses and CMS should not specify one over the others, e.g. specifying ABTC certification.
- Dietician requirement. Compliance with this requirement will be met when the patient is an inpatient for the actual transplant process. If this is a requirement for the pre-transplant stage, during the evaluation, it will be onerous for the extra renal programs. Patients are cared for by their cardiologists and hepatologists. The TX programs see them for their evaluation, make recommendations and return them to their primary physicians. Recommendations as to weight control or loss to meet selection criteria will be addressed in communication to the primary physician and the patient. A dietary consult at this stage will be too expensive and will fractionate the patient's care. Cardiac diets, etc., should be under the direction and monitoring of the primary physician.

Organ Procurement (482.100)

- Transplant centers should notify the OPTN or UNOS if an OPO agreement has been terminated.

Patient and Living Donor Rights (482.102)

- Guidelines should be developed by experts in the transplant community and published by OPTN as a resource and used for UNOS to monitor. ACOT is an appropriate standard.
- OPTN guidelines should be used for notification of unavailability of surgeon.
- Informed consent process: This is not realistic. A patient may be on waitlist for 3 to 5 years. The informed consent process is gone through at the time of evaluation. The patient probably does not remember most of this by the time they are transplanted and there is usually not enough time to go through it prior to surgery (very extensive).
- As there are so many variations in program size and methods of functioning, each Transplant Center should be able to define its process and structure for donor advocacy utilizing its existing trained professionals in a way that promotes an unbiased advocacy for living donors. For example, the clinical social worker may be defined as the "donor advocate", consistent with the existing social work role/ function. Another example of program policy might be that the evaluating physician/social worker could be separate for the donor and for the recipient.
- It is difficult to imagine how a Transplant Center would find someone, outside of its realm and professional expertise, who would have the knowledge, capacity and effectiveness to function as a Donor Advocate as intended by the statute. Furthermore, if the Center contracts with such an individual, then the contractual arrangement in itself could be viewed as a conflict. Another option would be to have UNOS be the gatekeeper by setting up an Ombudsman type component (similar to nursing home models) which would be a resource available to all donors nationwide.
- Patient Selection Criteria—requirement that patients should be specifically educated to the selection criteria. CMS should not dictate or be prescriptive. Each patient is unique and selection criteria need to be applied individually to each. Selection criteria are never absolute. The selection committee decision can be very subjective; it is not black and white. This requirement could be detrimental to patients, make them give up hope or loose confidence.
- Requirement of informing patients of certain risk factors: Question—how will each patient be alerted to specific donor risk factors—in the case of a deceased donor it is a matter of hours before the transplant that the specific information about the donor is known. The patient is being brought in for transplant, taken to the OR, and prepped. The transplant coordinator is often not present. This is not the time to be discussing specific donor risk factors. This requirement will be difficult to implement.

Additional Requirements of Kidney Transplant Centers (482.104)

- Kidney transplant should remain associated with the ESRD network for comprehensive ESRD oversight.

Alternative Process to Re-Approve Transplant Centers

- It would be appropriate for CMS to base decisions about the need to conduct individual transplant center surveys on information provided by the OPTN.
- The OPTN should be the entity to survey transplant programs as it is already reviewing programs every three years for compliance with listing policies. The OPTN has the data and sets the standards for practice.
- Programs who are already Medicare certified should be recertified if they meet the first two requirements, i.e. data submission and outcomes. The third requirement, processes, can be reviewed when the OPTN comes for their scheduled review.

General comments

- Any survey is a duplication of efforts as UNOS already surveys the transplant centers every 3 years for most aspects included in the document.
- Any additional survey requirements should be delegated to the OPTN
- UNOS approval for participation meets the personnel requirements for transplant centers and should be the standard.
- The centers that would fall out as not meeting requirements (based on data submission, outcomes) are already easily identified (approximately 10%). It would be more appropriate and less costly to address the centers already not meeting criteria than requiring the 90% of centers who already meet or exceed the criteria to spend the time documenting what is already known.
- The centers not meeting the criteria should have to complete the documentation for COP and the other centers should be grandfathered in as meeting the criteria
- Kidney programs should not be considered for the same initial approval criteria. Because kidney transplants are the majority of either Medicare primary or Medicare secondary as the payer, it would be difficult to transplant nine non-Medicare patients. The current approval process is for one patient to be transplanted and then conduct an onsite survey to validate requirements are met. This should not change.
- The elimination of Medicare immunosuppressant coverage for the life of a transplant when performed at a non-Medicare approved facility is detrimental to the long term outcomes of transplant patients and is a disincentive for new programs to be initiated. This restriction should be eliminated before any extension is added to the timeframe to qualify as and approved transplant center. Even if a patient is transplanted at a non-Medicare facility, they should be allowed Medicare immunosuppressant coverage.
- Will the 3 yearly data submission(s) to CMS be performed on line?

- If the OPTN is not used to administer and implement this regulation it will require the establishment of a complete new monitoring entity familiar with transplant programs and transplant policies. I believe the $300,000 additional expense quote is not an accurate estimation.

Submitter : Mr. Albert Newmann **Date:** 06/03/2005

Organization : Organ Donor Center of Hawaii

Category : Organ Procurement Organization

Issue Areas/Comments

Issues

OUTCOME MEASURE REQUIREMENTS

Dear CMS Officials:

I am thankful for the opportunity to comment on the proposed CMS rule 3835-P regarding Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants.

As the Hospital Services Manager for the Hawaii organ procurement organization, I have observed that our local transplant hospital, as well as many transplant hospitals in the nation, consistently lag behind state and national performance norms regarding the PROCUREMENT process. I refer specifically to the process measures of timely referral of imminent death, appropriate approach of the donor family, and most telling, the outcome measure of conversion rate, the newest JCAHO survey standard.

It is our observation that transplant hospitals focus intently on the RECEIPT of organs for transplant, while virtually ignoring their dual responsibility as a SOURCE of organs for transplant. They consistently have patients who meet eligible donor criteria, yet also consistently fail to refer them in a timely manner, or approach the family in sub-optimal fashion, resulting in conversion rates at the low end of the acute care facilities in the service area. Meanwhile, their low receptivity to the counsel of their local OPO regarding the procurement process aggravates the situation, preventing access to current 'Best Practices'.

My proposal is this: that CMS set an outcome measure requirement for transplant hospital conversion rates at a minimum 60%, with a goal of 75%, in line with the standard set for the nation's largest hospitals in the HHS Organ Donation Breakthrough Collaborative. I would also mandate that these transplant hospitals counsel with their local OPO regarding how to reach those standards by implementing Best Practices proven effective by the HHS Organ Donation Breakthrough Collaborative.

Because it is the recognized center of transplantation in the community, the transplant hospital is positioned to exert considerable impact on the healthcare community's transplant-related practice. Procurement is transplant-related. That they fail to take the lead as the standard bearer in the procurement process is both a mystery and a waste of valuable resource. I therefore request that CMS employ its power of authority to 'encourage' the transplant hospital to take it's rightful place as the transplant thought and practice leader in the community.

Thank you for this opportunity to comment.

Albert Newmann
Hospital Services Manager
Organ Donor Center of Hawaii

Submitter : Carla R. Williams **Date: 06/03/2005**

Organization : New York Center for Liver Transplantation

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

MS Word attachment

CMS-3835-P-22-Attach-1.DOC

Attachment #22
March 24, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
PO Box 8013
Baltimore, MD 21244-8013

RE: Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants

The New York Center for Liver Transplantation, Inc. (NYCLT) is a not for profit organization comprised of the five liver transplant programs in New York State. Established in 1988, our mission has been to assure the quality of care delivered to patients receiving liver transplant services. As such, we applaud CMS for its efforts in revising the requirements to ensure that transplant centers continually provide high-quality transplantation services in a safe and efficient manner. While we agree with a great many of the proposed changes, we have several comments as outlined below.

OUTCOME MEASURE REQUIREMENTS (482.80/482.82)

- Patient and graft survival outcomes are appropriate measures of transplant center performance. However, the data collected by OPTN to be used in SRTR analysis of center-specific reports is not all-encompassing. For example, steatosis is not consistently or accurately captured for all liver donors on the OPTN data collection forms, yet literature shows steatosis may have an impact on liver transplant outcomes.

- Using the "average" or the norm as a measure of comparison is also problematic, specifically in those regions where access to quality organs, particularly livers, is limited. In these circumstances, organs having a higher relative risk are often used to prevent the death of a wait-listed patient. Factors such as the size of the waiting list, the number of organ donors and the number of deaths on the waiting list in each region need to be included in the analysis. Otherwise the proposed system may inhibit the use of organs having higher relative risk, thereby keeping outcomes high, but increasing the number of deaths on the waiting list at the same time.

PATIENT AND LIVING DONOR SELECTION (482.90)

- The selection of living liver donors in New York State is governed by state regulation. While medical suitability of the living donor must be ascertained and documented by the Independent Donor Advocate Team (IDAT), all such records and documentation must remain separate and distinct from the potential recipient medical record. The proposed requirement that documentation of living donor suitability for donation be in the potential recipient record is a breach of confidentiality and a violation of New York State regulation.

HUMAN RESOURCES (482.98)

- The first Condition of Participation in the proposed rule requires that a transplant center be a member of and abide by the rules and requirements of the OPTN. Currently, a member in good standing of the OPTN must meet professional standards and personnel requirements.

As such, it would seem that the Condition of Participation related to Human Resources is redundant.

PATIENT AND LIVING DONOR RIGHTS (482.102)

- Potential living donors should have access to a multidisciplinary team whose main responsibility is to safeguard the interests and well-being of the donor. This Independent Donor Advocate Team can help to ensure continuity of care during the pre-donation, donation and post-donation phases.

- The informed choice process is a critical element of living donation and should be presented in a manner that is understandable to a potential donor and consistent with his or her language and educational level.

- Potential living donors should be given adequate time to understand and assimilate the information provided. For example, New York State regulation provides potential living liver donors with a minimum two-week reflection period between the time when a potential donor is informed of his or her suitability for donation and the time when the potential donor makes a final decision.

- All potential living donors should have the right to make this decision in an environment that is free from coercion.

SPECIAL PROCEDURES FOR APPROVAL AND RE-APPROVAL OF ORGAN TRANSPLANT CENTERS (488.61)

- Existing transplant centers are subject to UNOS surveys on professional standards and surveillance. Those centers who meet outcomes and submission requirements should not be subject to an initial CMS survey as this effort is duplicative. However, new or existing transplant centers who do not meet the outcomes and submission requirements should be subject to an initial CMS survey.

- The proposed rule should provide for a period of remediation during which a transplant center may develop, submit and implement a plan of correction. Upon completion of the remediation, a transplant center must meet 1-month expected outcomes and be resurveyed.

ALTERNATIVE PROCESS TO RE-APPROVE TRANSPLANT CENTERS

- Transplant centers should be approved based on graft and patient survival outcomes specific to each center. An alternate process of re-approval based on random surveys and OPTN input is not a consistent or efficient way to measure transplant center performance.

Thank you for your consideration of these comments.

Sincerely,

Carla R. Williams
Executive Director

Submitter : Ms. Lori E. Brigham **Date:** 06/03/2005

Organization : Washington Regional Transplant Consortium

Category : Organ Procurement Organization

Issue Areas/Comments

GENERAL

GENERAL

Comments on Proposed Rule: Hospital Conditions of Participation; Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplant, CMS 3835-P, 70 Fed.Reg. 6140 Feb 4, 2005. Comments are attached in PDF format. Lori Brigham, CEO WRTC 703-641-0100.

CMS-3835-P-23-Attach-1.PDF

Attachment # 23

WASHINGTON REGIONAL TRANSPLANT CONSORTIUM

June 3, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS 3835-P
PO Box 8015
Baltimore, MD 21244-8015

Re: ***Washington Regional Transplant Consortium***
***Comments on Proposed Rule – Medicare Program: Hospital Conditions of Participation; Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants*, CMS 3835-P, 70 *Fed. Reg.* 6140 (February 4, 2005)**

Dear Sir or Madam:

The Washington Regional Transplant Consortium ("WRTC") is submitting comments in the above referenced rulemaking proceeding to reinforce comments that WRTC is submitting on the issue of organ recovery team privileging (proposed §486.326 (a) (3) in the separate rulemaking proceeding. *Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations ("OPOs", 70 Fed. Reg. 6086 (February 4, 2005).* In particular, WRTC invites the Centers for Medicare & Medicaid Services ("CMS") to consider its comments on the following proposed regulation:

1. ORGAN RECOVERY AND RECEIPT
(Proposed §482.92)

WRTC's comments are attached to this letter. See, WRTC COMMENTS attached. If you have any questions or require additional information, please contact me at: Tel. 703 641 0100

Sincerely,

Lori E. Brigham
Chief Executive Officer

Enclosure: As stated

[illegible]

Washington Regional Transplant Consortium
Comments on Proposed Rule
Medicare Program: Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants
CMS 3835-P, 70 *Fed. Reg.* 6140 (February 4, 2005)

COMMENT 1. ORGAN RECOVERY AND RECEIPT (Proposed §482.92)

This proposed regulation addresses serious issues. In WRTC's view, however, CMS should go further and use the opportunity presented by this rulemaking proceeding to address an issue that has not yet given rise to any adverse publicity for the organ donation system, but which presents potentially serious problems that could be pre-emptively addressed in this proceeding. The issue is recovery team privileging and the responsibility of transplant centers for dispatching qualified personnel to perform organ recoveries. Transplant centers frequently provide recovery teams to perform organ recoveries on donors identified by OPOs. Currently, CMS does not require those transplant centers to send qualified personnel. The instant rulemaking does not address this issue. This proposed regulation, §482.92, is an opportunity to do so.

In the separate rulemaking proceeding, *Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations ("OPOs"), 70 Fed. Reg. 6086 (February 4, 2005),* CMS proposed a new regulation, §486.326 that provides, among other things:

> *(3) The OPO must have credentialing records for physicians and other practitioners who routinely recover organs in hospitals under contract or arrangement with the OPO and ensure that all physicians and practitioners who recover organs in hospitals with which the OPO has agreements are qualified and trained.*

§486.326 (a) (3) Condition: Human Resources

This proposed regulation (referred to hereafter as "OPO PR") correctly recognizes the importance of ensuring that "recovery personnel are qualified to recover organs in a manner that preserves their viability for transplantation." The OPO PR also correctly appreciates that donor hospitals would experience great difficulty in overseeing the qualifications of organ recovery teams, especially when recovery personnel may come from another jurisdiction or perform recoveries only infrequently at the particular hospital. The OPO PR's solution to this problem is to require OPOs to maintain credentialing records on those individuals who routinely perform recoveries in its service area and to require the OPO to ensure that individuals who perform recoveries in hospitals with which the OPO has agreements are trained and qualified.

WRTC endorses CMS's goal in proposing the requirement outlined above. It is imperative that organs be recovered in a proper manner and it is tragic, and inexcusable if inexperienced or incapable recovery personnel compromise the viability of any organ. Accordingly, WRTC believes that CMS should address this issue in the most effective way possible. The OPO PR does not accomplish this goal because it ignores the crucial role played by the transplant hospitals.

Washington Regional Transplant Consortium

Comments on Proposed Rule

Medicare Program: Hospital Conditions of Participation; Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants

CMS 3835-P, 70 *Fed. Reg.* 6140 (February 4, 2005)

The OPO PR appears to propose a dramatic expansion in OPO responsibilities without giving proper consideration to whether that expansion is desirable or capable of implementation. Currently, WRTC does not have sole responsibility for all aspects of recovery team credentialing. Many transplant centers and surgeons regard organ recovery as an integral part of patient care -- of their responsibility to the organ recipient. As part of this responsibility, they generally dispatch their own teams to perform the recovery and determine whether recovery team members are appropriately qualified. WRTC facilitates the recovery process by acting as a clearinghouse for recovery team qualifications. WRTC accords the recovery team recovery privileges in the donor hospital based on the statement of credentials provided by the sending institution. The OPO PR now seems to require OPOs to assume responsibility for all phases of the credentialing process i.e. determining the competence of recovery personnel and arranging for recovery personnel to receive privileges at the donor hospital. OPOs do not have readily available to them the staff and expertise to maintain a full fledged credentialing operation. The Notice of Proposed Rulemaking ("NOPR") contains no discussion of how CMS anticipates that OPOs will carry out this new function.

In placing responsibility on the OPO, the OPO PR overlooks a crucial fact – OPOs lack the leverage and authority to enforce compliance upon hospitals and transplant staff. The OPO PR also fails to place responsibility where it belongs - with the entity that *does* have the leverage and authority to require compliance -- most often the transplant hospital that dispatches the recovery team.

WRTC already has a standing policy that only properly qualified personnel may recover organs in its service area. WRTC routinely contacts sending hospitals, those inside its service area as well as outside its service area, to request appropriate verification of recovery team qualifications. From time to time, sending institutions disregard WRTC's policy. Hospitals or transplant staff may send an individual to perform a recovery without also providing documentation of that individual's qualifications for the task. In other instances, an individual arrives with privileging documentation that does not adequately or accurately describe that individual's qualifications to perform the recovery for which he or she has been sent. By their very nature, recoveries cannot be planned or scheduled more than several hours in advance and the issue of privileging tends to arise when the recovery team is in transit to the donor hospital, or has already arrived, and it is late at night or on a weekend or outside normal business hours – in short, when the time and resources available to resolve the problem are extremely limited. WRTC's efforts to obtain timely information from the sending institution have been largely unsuccessful. In these circumstances, the OPO is confronted with invidious choices – it can permit the unprivileged individual to proceed with the recovery. If it does so, there is a twofold risk: (i) that, through an error of omission or commission, the unprivileged individual will compromise the organs he or she is sent to recover, with the resulting potential harm to the intended recipient; and (ii) that, through an error of omission or commission, the unprivileged individual will damage the organs intended for other recipients, with the resultant harm to a

wider circle of intended recipients. These risks potentially expose the OPO to tort liability for having a policy it did not implement.

On the other hand, if the OPO reschedules the recovery to enable qualified recovery personnel to be dispatched, there is again a risk that all the organs will be compromised by the delay; and the organ distribution process itself will be disrupted by the resulting need to reschedule other coordinated organ recoveries from that donor. Moreover, donor hospital operations will be disrupted. Such disruption harms the OPO's relationship with the donor hospital and likely damages the cooperation on which the OPO is dependent for its effectiveness. All of these possibilities would harm patients waiting their turn to receive an organ – it harms their chances of receiving an organ, or their chances of receiving the best possible uncompromised organ. These risks potentially expose the OPO to tort liability for having a policy that caused such predictable collateral damage.

If the OPO responds to these privileging failures after the event and suspends the privileges of the hospital or transplant surgeon who sent the undocumented or unqualified recovery staff, the most likely result will be to disrupt the orderly recovery and distribution of organs and tissues in the OPO's service area. Most importantly, the potential recipients who are the patients of the affected transplant programs may be harmed when organs they may have received are sent elsewhere. OPOs can facilitate and coordinate the privileging process but they lack the leverage to compel compliance. The OPO PR would not improve that situation.

WRTC is in the fortunate position of having a medical director who attends, or sends a substitute to attend, all organ recoveries in the WRTC service area. The medical director can intercede when the recovery team is obviously unqualified. This solution is not ideal because it may expose the OPO to tort liability for any poor outcome experienced by the recipient of that organ. Moreover, this solution is not available or suitable for all OPO service areas.

WRTC believes that CMS can most effectively address this problem by imposing a Condition of Participation (CoP) on those transplant centers that send out recovery teams. That CoP should require the pertinent hospitals to have a policy and procedure. That policy and procedure should: specify that the hospital will send only qualified recovery team personnel. In WRTC's experience, different institutions have different ideas about the training and experience required to be considered "qualified". Accordingly, the policy and procedure should specify with particularity, the training and experience the sending institution requires before recovery personnel will be deemed "qualified" – e.g. the number of supervised recoveries performed, knowledge of OPO recovery protocols, including any protocols on multi-organ recoveries, and pertinent knowledge about the intended recipient. Further, the policy and procedure should require hospitals to provide the OPO with information about recovery staff qualifications in advance of any recovery, and should require hospital staff to respond promptly to OPO requests for information. It should also provide for discipline in the event of non-compliance. Backed by such a regulation, WRTC would be better able to carry out the task of ensuring that appropriately

qualified recovery teams receive privileges to perform their recovery function at donor institutions.

Further WRTC, believes that this issue is of sufficient importance that the Organ Procurement and Transplantation Network ("OPTN") should be asked to develop policies for recovery team qualifications that OPTN members would be required to follow as a condition of membership in the Network. The OPTN is responsible for increasing the effectiveness and efficiency of organ sharing and for increasing the supply of donated organs available for transplantation. It accomplishes this mission by, among other things, developing policies that reflect a national consensus on issues affecting organ recovery. Recovery team qualifications are an appropriate area for national standard setting because mistakes by recovery team personnel can have a direct impact on the number and quality of organs available for recipients. Moreover, a national standard is desirable because different transplant programs have different ideas about the qualifications required to perform a recovery. These differing views may create problems, particularly in the multi-organ recovery context, where cooperation and understanding of the needs of other organ recovery teams are of paramount importance. A national standard would largely eliminate the opportunities currently available for the use of temporary or convenient calculations of the amount of training and experience required before a recovery team is considered qualified. The Department of Health and Human Services ("HHS"), unlike individual OPOs, is in the best position to recommend that OPTN take action on this important issue.

WRTC has made this same comment in the CMS rulemaking proceeding, *Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations ("OPOs"), 70 Fed. Reg. 6086 (February 4, 2005)*. WRTC is reiterating its comment here because transplant hospitals have a significant role to play in ensuring that recoveries are carried out by qualified personnel. WRTC requests that CMS include in proposed §482.92 a requirement that transplant hospitals ensure that recovery personnel are properly credentialed. The inclusion of such a requirement would greatly assist OPOs to carry out their coordinating function.

Submitter : Mr. Paul Schwab **Date:** 06/03/2005

Organization : Association of Organ Procurement Organizations

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3835-P-24-Attach-1.DOC

AOPO
Association of
Organ Procurement
Organizations

Attachment #24
June 3, 2005

Mark B. McClellan, MD, PhD.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
P.O.Box 8013
Baltimore, Maryland 21244-8013

Dear Dr. McClellan:

We are pleased to take this opportunity to respond to the proposed CMS rule (CMS-3835-P) regarding Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform organ Transplants. The Association of Organ Procurement Organizations (AOPO), as you know, represents all fifty-eight federally designated OPOs in the country.

Under separate cover, AOPO has responded to CMS-3064-P regarding Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations. Several of our comments which follow cross reference these two proposed regulations.

(1) In the interest of advancing organ donation and transplantation, it is essential that there be regulatory incentives in these two rules which are positively aligned and do not conflict with one another. Specifically, the proposed OPO rules provide added outcome performance incentives for OPOs to recover organs from donation after cardiac death (DCD) and older donors. It would appear, however, that patient and graft survival measures advanced for transplant centers may not be in congruence in offering positive incentive for utilizing organs from these donors for transplant. We would strongly recommend remedying this conflict in a manner supportive of increased recovery and transplantation, that is, providing incentives in both regulations that positively reinforce recovery and transplant of organs from such donors.

(2) Both rules are characterized by very detailed and prescriptive process measures. In the AOPO response to CMS-3064-P, we recommended that the proposed quality assessment and performance improvement (QAPI)

provisions serve as a model for approaching process measures generally. This would apply to process measures proposed for both organ procurement organizations and transplant centers, as the science of procurement and transplantation continually evolves and an overall organ procurement and transplant network structure and framework already exist to achieve timely concordance between changing policy and practice.

(3) In view of the new, generally stated appeals approach advanced by CMS for organ procurement organizations, we note with interest the absence of any specific appeals mechanism proposal in the regulation regarding transplant centers. We would submit that there be symmetry between the appeals processes available to both OPOs and transplant centers. OPOs currently have the right to appeal a de-certification under §498. The proposed OPO regulations would replace the 498 appeals process with a separate, new appeals process. From a procedural standpoint, the 498 appeals process provides the OPOs with fairness and stability. We would submit that the 498 appeals process be the appropriate mechanism for OPOs and transplant centers alike.

(4) There are occasions when OPOs have experienced difficulty in obtaining follow-up data on transplant recipients from physicians caring for these recipients or from some transplant centers. The reluctance is occasioned by an erroneous belief by some providers that providing such information would violate the Health Insurance Portability and Accountability Act ("HIPAA"). We would recommend that the rule clarify that follow-up data are essential for evaluation of outcomes, the refinement of organ allocation policies, the reporting of outcomes to UNOS, and the capability of OPOs to OPOs to anonymously inform donor families of the viability of their loved one's organs, and that the release of the data to transplant centers, OPOs, and/or to the OPTN/UNOS does not constitute a violation of the HIPAA privacy regulations.

(5) The regulations are dated regarding reference to "Department (of HHS) Activities Related to Organ Donation and Transplantation." Specifically, the rule summarizes former Secretary Thompson's multi-level approach to increasing organ, tissue, and marrow donation but makes no reference to either the ongoing HHS Organ Breakthrough Collaborative or the upcoming HHS Organ Transplantation Initiative. The latter has major implications for the participation of donor hospitals, organ procurement organizations, and transplant centers. We would recommend that the final rule incorporate reference to the initiative regarding increasing organs transplanted per donor and provide positive incentives for participation.

(6) We note with interest the statement in the rule: "We (CMS) applaud the SRTR's effort to strive for better ways to identify under-performing transplant centers." We similarly applaud the work of SRTR regarding donation rate

methodology and assessment and have brought that matter to the attention of CMS in our response to CMS-3064-P. In both instances, we believe that determinations of "under performance" should not be solely based on approaches that arithmetically lead to organizations automatically falling out each performance cycle. The inclusion of a statistically-based methodology as part of outcomes measurement, such as the analytic work of the SRTR, remedies the shortcomings of any automatic fall-out approach.

(7) The OPO regulations, in response to legislative mandates in the Pancreatic Islet Cell Act of 2004, include incentives for pancreas recovery for islet call transplantation and research. The regulation for transplant centers, in contrast, exclude islet procedures from proposed pancreas standards.

(8) We recommend that the proposed organ recovery and receipt requirements call for consistency with OPTN policies and procedures and not incorporate additional, prescriptive standards which are likely to evolve and be dealt with in the existing OPTN framework.

(9) We support the provision requiring that transplant centers "establish and implement a written policy to address adverse events that occur during any phase of the organ transplant process." A similar provision should be advanced for OPOs, rather than the proposed detailed reporting system outlined in CMS-3064-P. Here as well the principle of symmetry between OPO and transplant center regulations, to the maximum extent appropriate, should be pursued.

(10) We support the proposal "to require that transplant centers ensure that the transplant hospital in which the center operates has a written agreement for the receipt of organs with an OPO designated by the Secretary."

Thank you again for this opportunity to comment.

Sincerely,

Joseph Roth
President

Paul Schwab
Executive Director

Submitter : **Date: 06/03/2005**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-3835-P-25-Attach-1.PDF

Attachment # 25

June 3, 2005

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–3835–P, PO Box 8013
Baltimore, MD 21244–8013

We have the following comments regarding proposed transplant center conditions of participation (CMS Docket ID: CMS-3835-P - Requirements for Approval and Reapproval of Transplant Centers to Perform Organ Transplants):

1. The Scientific Registry for Transplant Recipients (SRTR) reports two-sided p-values in the Center-Specific Reports (CSRs) because these reports are intended to identify centers with both good and poor outcomes. The one-sided p-value, in the proposed CMS regulation, is appropriate for identifying centers with poor outcomes. The one-sided p-value is calculated based on the Poisson distribution as the probability that there are more than, or equal to, the observed count of adverse events based on the expected number of events at each facility. The one-sided p-value can be calculated by dividing the two-sided p-value by 2, for those facilities with worse than expected outcomes. The SRTR has added (as of the July, 2005 release) the following components to the publicly available SRTR CSRs: counts of observed failures/deaths and counts of expected failures/deaths. Both the one-sided and the two-sided p-values are calculated from these observed and expected counts.

2. The proposed rule materials explain the importance of using risk-adjustment when comparing observed to expected mortality during the follow-up period (possibly with different follow-up periods for different patients). Use of the data throughout the follow-up is different from calculating and comparing the observed to the expected fraction surviving at a particular time point, such as at 1 year. Use of the data throughout the follow-up usually gives more statistical power (sensitivity) than does the evaluation of a survival curve at a particular time point.

3. The criterion of more than 3 excess deaths (observed minus expected > 3) was set by the Organ Procurement And Transplantation Network (OPTN) Membership and Professional Standards Committee (MPSC) and SRTR as a meaningful threshold of the number of excess deaths that made the difference "important". The criterion for an "important" difference depends upon the choice of cohort and duration of the follow-up period. For example, 3 excess deaths in 1 month are more important than 3 excess deaths over a period of 3 years; 3 excess deaths among a 1 year cohort of transplants is more important than 3 excess deaths among the transplants performed over several years. Very few facilities will accrue as many as 3 excess deaths in a very short follow-up, for example one month. The OPTN MPSC committee uses a 2 year cohort for evaluating center outcomes. The proposed CMS rule is based on the public SRTR CSR, which uses a 2.5 year cohort. The use of different cohort lengths will lead to different results when centers are reviewed.

4. Quantitative methods similar to those in the proposed CMS regulations were developed by the SRTR contractor for use by the OPTN MPSC. Those quantitative measures serve as a screening tool to trigger a review process with a mechanism for a response by centers that are reviewed. While these quantitative tools are useful for identifying centers with mortality that is higher than expected, based on the best available statistical models, these tools cannot account for patient-mix factors that are not measured or are not included in the statistical model. By using the quantitative tools in conjunction with a review-response process, the MPSC is able to recognize and accommodate such potential limitations of the statistical models.

Sincerely,

Friedrich K. Port, MD, MS
President, University Renal Research and Education Association (URREA)

Robert M. Merion, MD
Professor of Surgery, The University of Michigan Medical School

Robert A. Wolfe, PhD
Professor, Department of Biostatistics, School of Public Health, The University of Michigan

Submitter : Ms. Casandra Smith-Fields **Date:** 06/03/2005

Organization : Children's Memorial Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Using the term transplant center interchangeably with transplant program is unnecessarily confusing. The language needs to be consistent throughout the document. We would recommend the use of transplant program. Many transplant hospitals run multiple transplant programs - ie kidney, liver, heart, etc. However, they never refer to themselves as running multiple transplant "centers". The term transplant center is commonly used interchangeably with transplant "hospital" - so, to avoid confusion it should be removed from this document.

Submitter : **Ms. Casandra Smith-Fields** **Date: 06/03/2005**

Organization : **Chidren's Memorial Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

"see Attachment"

CMS-3835-P-27-Attach-1.DOC

Attachment #27
CMS – 3835-P Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplant

CRITERIA FOR CENTERS PERFORMING PEDIATRIC TRANSPLANTS
"We are not requiring a minimum number of transplant (adult or pediatric) for pediatric centers". Our opinion is that some minimal volumes need to be utilized for each organ type to ascertain the commitment and investment of the hospital to the transplant program in a pediatric center. Ten is a realistic annual volume for pediatric liver and kidney programs. The annual volume for pediatric heart programs is much lower and should include a calculation for open and closed congenital heart surgeries performed by the heart transplant surgeons.

PATIENT AND LIVING DONOR SELECTION
It is proposed that a prospective transplant candidate must receive a psychosocial evaluation prior to placement on the waitlist. This proposal is not practical in several situations. First, in fulminate hepatic failure and acute cardiomyopathy the patients present in such an acute state that psychosocial evaluations cannot be performed prior to intubation/listing and transplantation. Secondly, in pediatrics when the patients are infants and small children on whom are you requesting that the evaluation be performed – the patient? The family? Why are you making this a requirement for listing?

HUMAN RESOURCES
The proposed regulations call for the director of a transplant hospital to be responsible for "ensuring adequate training of nursing staff in the care of transplant patients" - and yet you indicate that the director the transplant center will be either a primary surgeon or physician. Nurses do not report to physicians within hospitals and physicians do not train them – their body of knowledge is separate and distinct. It would be more appropriate to state that the transplant hospital is responsible for ensuring that the nursing staff receives adequate training in transplantation.

HUMAN RESOURCES
"We proposed that a qualified clinical transplant coordinator would have to be certified by the American Board of Transplant Coordinators (ABTC) which requires at least 12 months of work experience as a transplant professional in vascular organ transplantation and successful completion of the certification examination". We do not believe this proposal is appropriate – especially for a pediatric facility. Our hospital which operates four solid organ and one stem cell transplant program employs 100% Pediatric Advanced Practice Nurses. The first screen in hiring is pediatric experience as an APN. Secondly, we look for experience in the field of transplant science into which we are hiring. We almost never find both. We will teach the sub-specialty of transplant – we will not teach the pediatrics – that is considered the level of entry. Within two to three years our nurses are able to sit for certification exams and in fact currently sit for the NATCO nursing exam which we find to be much more relevant to their practice. This criterion needs to be removed.

ALTERNATIVE PROCESS TO RE-APPROVE TRANSPALNT CENTERS

Data used to determine certification and re-certification by CMS for transplant centers should be collected utilizing the UNOS standardized RFI. The UNOS Transplant Administrators committee has labored diligently over the past several years to convert the private payor industry to this data collection tool. It contains both the SRTR and programmatic data that CMS needs to certify a program. CMS in its efforts to be congruent with the OPTN/UNOS and eliminate/reduce paperwork should work with the standardized tool developed and accepted by the majority of payors in the US at this time.

Submitter : **Dr. Theodore Schrock** **Date: 06/03/2005**

Organization : **California Transplant Donor Network**

Category : **Organ Procurement Organization**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3835-P-28-Attach-1.TXT

Submitter : Mr. Alexander Aussi **Date:** 06/06/2005

Organization : CHRISTUS TRANSPLANT INSTITUTE (TXRM)

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3835-P-29-Attach-1.DOC

Attachment #29

CHRISTUS
Transplant Institute

COMMENT SUBMISSIONS
CMS-3835-P

June 5, 2005

OUTCOME MEASURE REQUIREMENTS:

1. There is even greater pressure on the infrastructures of transplant programs to meet the data reporting requirements within proposed timelines. There needs to be clearer guidelines for data coordinator functions (qualifications, volume expected per data coordinator...) as well as defined means for reimbursement of data reporting costs. Currently only Pre-Transplant related times are allowable on the cost report. Would there be a consideration for the data coordinator(s) to be considered under organ acquisition at 100% of administrative time?

2. The proposals do not take into account a Transplant center's outcome while involved in IRB approved research trials. Newer immunosuppression protocols may impact the centers' graft survival and would require that Research be factored in as a risk adjustment.

3. While this process for establishment of clear and current outcome requirements is much appreciated and long awaited, there needs to be a remediation process for transplant programs equally detailed in the regulation. The OPTN has an existing remediation process and would recommend that any new regulation on outcomes requirements be made in consultation with the OPTN. we also recommend to empower the OPTN in performing more comprehensive audits, with a preference to keeping all performance audit processes exclusively as an OPTN responsibility.

PATIENT AND LIVING DONOR SELECTION:

1. CMS proposals hereby detail requirements for Living Donor Management in the absence of National Coverage determinations on living donation in extra-renal organs. We recommend CMS National Coverage determinations on living donation in extra-renal organs at the same time of approving Liver Donor management strategies.

2. Patient and donor selection criteria should only serve as guidelines. There remain some cases where patients are turned down although the criteria elements may be met. This happens due to combination of shortcomings too varied to be codified.

We recommend that the ultimate decision to select a patient or to maintain the patient's suitability as a transplant candidate be that of the Transplant multidisciplinary team.

HUMAN RESOURCES

1. While there appears to be a mutual understanding of the need for each transplant program to have multidisciplinary personnel meeting the needs of their population, CMS proposals only list a few. While the transplant Medical Director, Social services and nutrition specialists are key to any transplant patient's successful journey through the transplant process, listing these few is greatly understating the need. We would recommend CMS using the UNOS requirements for identifiable transplant team members which are higher standards.

2. By Transplant Program standards, A Qualified clinical transplant coordinator is a licensed nurse (RN or Vocational) who underwent extensive training with the transplant medical team and has developed onto becoming a resource for the rest of the hospital staff. By default the transplant coordinators become the higher paid associates in the nursing salary lines which is making them a scarce and thought-after resource by transplant programs. Placing a requirement to qualify for the title with an ABTC exam does not necessarily ensure quality of care provided, but makes it harder to hire staff.
   While the ABTC exam provides a well rounded transplant test summary, it does not qualify a transplant coordinator. Other nursing subspecialty certifications may also be considered as pertinent to determine qualification (Critical Care, Case management...)in addition to time of service with the transplant team.

3. It remains unclear whether a minimum of One "qualified" transplant coordinator is only required per program or multiple.

4. Additional Requirements of Kidney Transplant Centers (482.104): specifically proposes that kidney transplant centers must cooperate with the ESRD Network designated for its geographic area in fulfilling the terms of the network's current statement of work.
   It is recognized that the ESRD network is involved in resolving Transplant patient grievances. In order to assure exposure and understanding of to the Transplant process we recommend having the same "qualification" requirements of staff at the ESRD network level as would be imposed on transplant coordinators. Specifically, we are recommending CMS consider making a requirement for ESRD network staff to have a minimum of 12 months transplant experience, and a related certification upon hire. We believe this would further elevate the level of understanding of clinical transplant operations at the ESRD network level, in turn beneficial in responding to patient grievances in an educated, constructive and reasonable manner in lieu of uncoordinated over-reactions currently experienced.

PATIENTS AND LIVING DONOR RIGHTS:

1. Additional Requirements of Kidney Transplant Centers (482.104): specifically proposes that kidney transplant centers must cooperate with the ESRD Network designated for its geographic area in fulfilling the terms of the network's current statement of work.
   It is recognized that the ESRD network is involved in resolving Transplant patient grievances. In order to assure exposure and understanding of to the Transplant process we recommend having the same "qualification" requirements of staff at the ESRD network level as would be imposed on transplant coordinators. Specifically, we are recommending CMS consider making a requirement for ESRD network staff to have a minimum of 12 months transplant experience, and a related certification upon hire. We believe this would further elevate the level of understanding of clinical transplant operations at the ESRD network level, in turn beneficial in responding to patient grievances in an educated, constructive and reasonable manner in lieu of over-reactions currently experienced.

Should you have any questions or require additional information, you may contact me at (210) 705-6702 or by mail:

CHRISTUS TRANSPLANT INSTITUTE
Attention: Administrative Director
2829 Babcock Road, Tower One Suite #300
San Antonio, Texas 78229

Respectfully,

B. Alexander Aussi, RN, MBA
Administrative Director

Submitter : **Ms. Trisha Kurtz** **Date: 06/06/2005**

Organization : **JCAHO**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3835-P-30-Attach-1.DOC

Joint Commission

on Accreditation of Healthcare Organizations

Setting the Standard for Quality in Health Care

Attachment #30

June 6, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Comments on the proposed rule "Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants"

File Code: CMS-3835-P

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) appreciates the opportunity to comment on the proposed rule that would set forth requirements that heart, heart-lung, intestine, kidney, lung, and pancreas transplant centers must meet to participate as Medicare-approved transplant centers. Founded in 1951, the Joint Commission is the nation's oldest and largest standard-setting and accrediting body in health care. The Joint Commission evaluates and accredits more than 15,000 health care organizations in the United States, including the preponderance of our nation's hospitals. The Joint Commission is also active internationally and has provided consultation and accreditation services in over 60 countries.

Last year, as part of our Public Policy Initiative, the Joint Commission convened a roundtable of experts to frame the complex factors and issues that inhibit organ donation and compromise the well-being of living donors, and to identify solutions for addressing these problems. The roundtable met several times and participated in a nationwide conference on organ donation. The results of the roundtable's work have been published

in a white paper, entitled *Health Care at the Crossroads: Strategies for Narrowing the Organ Donation Gap and Protecting Patients.*[1] Among several recommendations to enhance the safety of the transplantation process, the roundtable called for establishing a national living donor registry to track complications and outcomes; increasing knowledge about the risks of such donations to donors; adopting safe practices and systems for protecting the safety of patients and the integrity of procured organs; and developing and applying standardized IT systems and evidence-based practices that support determinations of organ suitability for transplantation and improve the rate and quality of organ recovery.

The Joint Commission commends CMS for issuing a proposed rule that establishes quality standards for approval and re-approval of transplant centers participating in the Medicare program. It is evident that in the course of drafting the proposed rule, CMS staff had to address a myriad of complex issues associated with providing high-quality transplantation services in a safe and efficient manner. This letter addresses provisions in the background section and the following subparts:

- Definitions (§482.70)
- Conditions of Participation: Notification to CMS (§482.74)
- Conditions of Participation: Data Submission and Outcome Measure Requirements for Initial Approval and Re-approval (§482.80, §482.82)
- Conditions of Participation Process Requirements
    - §482.90 (Patient and Living Donor Selection)
    - §482.92 (Recovery and Receipt)
    - §482.96 (QAPI)
    - §482.98 (Human Resources)
    - §482.100 (Organ Procurement)
- Deeming Authority (§488)

If you have any question or require additional information regarding the comments provided below, please contact Trisha Kurtz, Director of Federal Relations at pkurtz@jcaho.org or Laura Blum, Associate Director, Federal Relations, at lblum@jcaho.org. Both Trisha and Laura can be reached by telephone at 202.783.6655.

[1] The paper can be found at http://www.jcaho.org/about+us/public+policy+initiatives/organ+donation+white+paper.pdf.

Joint Commission's Comments

Background Section

The Joint Commission strongly recommends that CMS interpret the provisions of section 1865 of the Social Security Act and regulation set forth in 42 CFR Part 488 to mean that only accrediting organizations that meet CMS's definition of a "national private accrediting organization" are eligible to "receive approval of deeming authority for the proposed hospital CoPs for transplant centers, if the accreditation organization demonstrates that it has the requirements for transplant centers that are at least as stringent as the proposed CoPs."

In addition, the Joint Commission encourages CMS to only grant deeming authority for the transplant centers to organizations that have deeming authority for hospitals. Because transplantation surgeries rely on a hospital's services and systems, evaluation of a transplant centers compliance with the CoPs must be done in the context of the hospital where the center is located. Organizations that accredit both the hospital and the transplant center are in the best position to ensure consistent quality oversight and avoid a fragmented arrangement.

The importance of such continuity was demonstrated recently when a medical mistake at a transplant center caused the death of organ recipient. The root cause analysis showed that not all members of the transplant team were sufficiently familiar with hospital processes that were critical to a successful transplantation. Investigators concluded that a failure to integrate services provided in the transplant center with those of the hospital directly contributed to this outcome. We believe that this situation highlights the need to only grant transplant center deeming authority to organizations that have hospital deeming authority.

Definitions (§482.70)

The proposed rule would standardize the usage of certain terms by suggesting definitions for transplant hospitals. Because there is widespread agreement that the standardization

of definitions improves communication, which can lead to a reduction in adverse medical events, the Joint Commission applauds CMS's effort. We would like to clarify a point, however, about the use of the term "adverse event." The proposed rule states that the definition for "adverse event" is derived from the Joint Commission definition of an adverse event. The Joint Commission defines sentinel event, but does not have an explicit definition for an adverse event.

- *A sentinel event* is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury includes the loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

Such events are called "sentinel" because they signal the need for immediate investigation and response. The terms "sentinel event" and "medical error" are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events.

- *A near miss* is used to describe any process variation that did not affect an outcome but for which a recurrence carries a significant change of a serious adverse outcome.

Such a "near miss" falls within the scope of the definition of a sentinel event but outside the scope of those sentinel events that are subject to review by the Joint Commission under its Sentinel Event Policy.

Other relevant patient safety event definitions used by the Joint Commission include:

- *An adverse drug event* is "a patient injury resulting from a medication, either because of a pharmacological reaction to a normal dose or because of a preventable adverse reaction to a drug resulting from an error;" and

- *A medication error* is "any preventable event that may cause inappropriate medication use or jeopardize patient safety."

Patient Safety Event Taxonomy

In response to the profound lack of agreement on definitions of things that go wrong in the health care environment, the Joint Commission developed a "Patient Safety Event Taxonomy." [2] There is agreement that the standardization of patient safety data would facilitate improvements in incident reporting, tracking, and analysis. The concept of a taxonomy combines terminology and the science of classification of things that can go wrong in health care, the reason why they occur, and the preventive strategies that can minimize their future occurrences. At its broadest application, the taxonomy describes processes that determine the quality of incident reporting, the effectiveness of reporting systems, and the success of intervention strategies. The Joint Commission has served as a consultant to the World Health Organization on taxonomy-related works and was recently awarded a two year contract by the WHO to create an international patient safety taxonomy based on the Joint Commission's Patient Safety Event Taxonomy. Refinements to the taxonomy are being supported by a grant from the Agency for Healthcare Research and Quality and the National Quality Forum is considering the instrument for consensus. To decrease confusion, improve patient safety and promote quality, the Joint Commission recommends that CMS adopt the patient safety event taxonomy for its Quality Improvement Programs.

Conditions of Participation: Notification to CMS (§482.74)

The proposed rule would require each transplant center to report immediately to CMS information on any significant changes that would affect its approval, such as an unusually large number of patient deaths during or shortly after transplant or the departure of key personnel. The Joint Commission recommends that CMS link these same notification requirements to the appropriate accrediting organization (e.g. JCAHO and AOA). Timely notification to the accrediting organization is essential to thoroughly

[2] Chang A, Schyve PM, Croteau RJ, O'Leary DS, Loeb JM. The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. *International Journal for Quality in Health Care* 2005: pp.1-11.

assess the situation and ensure prompt corrective action. Joint Commission requires hospitals to immediately report any changes in the information provided in the application for accreditation and any changes made between surveys. A hospital that experiences a significant change in ownership or control, location, capacity, or the categories of services offered must notify the Joint Commission in writing not more than 30 days after such changes.

OUTCOME MEASURE REQUIREMENTS

Condition of Participation: Data Submission and Outcome Measure Requirements for Initial Approval of Transplant Centers (§482.80)

The proposed rule requires transplant centers to report patient survival and graft survival rates. While the Joint Commission believes that these rates are important, when used alone they do not portray a robust picture of outcomes at a transplant center. Clearly a more comprehensive view of transplant center performance is needed to properly assess a facility and to encourage continuous quality improvement. We recognize that the development of such measures may be challenging (i.e., risk adjustment will be needed), but we strongly encourage CMS to continue to identify (or develop) sets of measures that capture a more complete picture of a transplant center's performance.

CMS proposes to use heart and lung survival rates that are being compared against standards that were developed in 1986 and 1995, respectively. There are no current standards for survival rates for kidney, pancreas, and heart-lung transplants. The Joint Commission agrees that CMS should update survival rate criteria that will be required for Medicare approval to ensure greater alignment with current standards of practice. The Joint Commission also encourages CMS to provide incentives for the development of standards for survival rates for kidney, pancreas, and heart-lung transplants.

Condition of Participation: Data Submission and Outcome Measure Requirements for Re-approval of Transplant Centers (Proposed §482.82)

Ongoing evaluation of transplant centers is imperative to ensure that the entity continues to provide transplantation services in a safe and efficient manner after its initial approval. It is in this context that the flow of the electronic submission of data is of critical

importance. Transplants centers will regularly update data to the Organ Procurement and Transplantation Network (OPTN) during the course of care and patient follow up. In the accreditation arena, it is important to monitor this data to recognize deviations in performance and respond appropriately. The Joint Commission has re-engineered its accreditation process to help guide our surveyors as they plan and conduct accreditation reviews. The new process—known as the Priority Focus Process (PFP)—uses data from a variety of sources- including previous survey findings, compliant data, ORYX core measure data and publicly available data such as MedPAR and OASIS- to customize our accreditation process for a specific institution, such as a hospital or home health agency. The PFP is a critical component of the Joint Commission's new accreditation process, which is designed to shift the focus from survey preparation and passing the triennial exam to continuous standards compliance and operational improvements in the provision of safe, high-quality care, treatment and services.

PATIENT AND LIVING DONOR SELECTION

Condition of Participation: Patient and Living Donor Selection: Patient and Living Donor Selection (§482.90)

This proposed requirement that a transplant center must use written patient selection criteria for placement on a waitlist is consistent with Joint Commission standards. The Joint Commission requires hospitals to implement policies and procedures developed with the medical staff's participation for procuring and donating organs and other tissues. Joint Commission surveyors evaluate compliance with this requirement by assessing "elements of performance," including the following--

- The hospital has an agreement with an appropriate organ procurement organization (OPO) and follows its rules and regulations.
- The hospital's policies and procedures identify the OPO with which it is affiliated.
- The hospital has an agreement with at least one tissue bank and at least one eye bank (as long as the process does not interfere with organ procurement) to cooperate in retrieving, processing, preserving, storing, and distributing tissues and eyes.
- The hospital notifies the OPO in a timely manner of patients who have died or whose death is imminent.

- In Department of Defense hospitals, Veterans Affairs medical centers, and other federally administered health care agencies, this notification is done according to procedures approved by the respective agency.
- The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, for tissue and eye donation.
- The hospital has procedures, developed in collaboration with the designated OPO, for notifying the family of each potential donor of the option to donate—or decline to donate—organs, tissues, or eyes.
- This notification is made by an organ procurement representative or the hospital's designated requester.
- Written documentation by the hospital's designated requester shows that the patient or family accepts or declines the opportunity for the patient to become an organ or tissue donor.
- The hospital's staff exercises discretion and sensitivity to the circumstances, beliefs, and desires of the families of potential donors.
- The hospital maintains records of potential donors whose names have been sent to the OPO and tissue and eye banks.
- The hospital works with the OPO and tissue and eye banks as follows:
    - In reviewing death records to improve identification of potential donors
    - To maintain potential donors while the necessary testing and placement of potential donated organs, tissues, and eyes takes place
    - In educating staff about donation issues

Hospitals performing transplant services are also assessed for compliance with the following elements of performance.

- A hospital transplanting human organs must belong to the organ procurement and transplantation network (OPTN) established under section 372 of the Public Health Service Act and must abide by its rules.
- If requested, the hospital provides all organ transplant-related data to the OPTN, the Scientific Registry, or the hospital's designated OPO.

Condition of Participation: Organ Recovery and Receipt (§482.92)

This CoP, requiring a protocol that a transplant center's organ recovery team would review and compare the recipient and donor data before recovery takes place, is a critical component to ensure that facilities are providing safe care. As noted in the proposed rule, there are not any provisions addressing procedures for transplant centers to ensure that donor organ and transplant recipient data are compared or to prevent the transplantation of mismatched organs. The Joint Commission encourages CMS to review our Universal Protocol as a potential model for a transplant center's organ recovery team.

Joint Commission's Universal Protocol

The Joint Commission developed the universal protocol as one of our National Patient Safety Goals. The protocol applies to all operative and other invasive procedures. The protocol is intended to prevent wrong site and wrong person surgery. It is based on the consensus of experts from the relevant clinical specialties and professional disciplines and is endorsed by nearly 50 professional medical associations and organizations. In developing this protocol, consensus was reached on the following principles:

- Wrong site, wrong procedure, wrong person surgery can and must be prevented.
- A robust approach—using multiple, complementary strategies—is necessary to achieve the goal of eliminating wrong site, wrong procedure, wrong person surgery.
- Active involvement and effective communication among all members of the surgical team is important for success.
- To the extent possible, the patient (or legally designated representative) should be involved in the process.
- Consistent implementation of a standardized approach using a universal, consensus-based protocol will be most effective.
- The protocol should be flexible enough to allow for implementation with appropriate adaptation when required to meet specific patient needs.
- A requirement for site marking should focus on cases involving right/left distinction, multiple structures (fingers, toes), or levels (spine).
- The universal protocol should be applicable or adaptable to all operative and other invasive procedures that expose patients to harm, including procedures done in settings other than the operating room.

In concert with these principles, the following steps, taken together, comprise the Universal Protocol for Eliminating Wrong Site, Wrong Procedure, Wrong Person Surgery:

Pre-operative verification process

Purpose: To ensure that all of the relevant documents and studies are available prior to the start of the procedure and that they have been reviewed and are consistent with each

other and with the patient's expectations and with the team's understanding of the intended patient, procedure, site and, as applicable, any implants. Missing information or discrepancies must be addressed before starting the procedure.

Process: An ongoing process of information gathering and verification, beginning with the determination to do the procedure, continuing through all settings and interventions involved in the preoperative preparation of the patient, up to and including the "time out" just before the start of the procedure.

Marking the operative site

Purpose: To identify unambiguously the intended site of incision or insertion.
Process: For procedures involving right/left distinction, multiple structures (such as fingers and toes), or multiple levels (as in spinal procedures), the intended site must be marked such that the mark will be visible after the patient has been prepped and draped.

"Time out" immediately before starting the procedure

Purpose: To conduct a final verification of the correct patient, procedure, site and, as applicable, implants.
Process: Active communication among all members of the surgical/procedure team, consistently initiated by a designated member of the team, conducted in a "fail-safe" mode, i.e., the procedure is not started until any questions or concerns are resolved.

Condition of Participation: Quality Assessment and Performance Improvement (§482.96)
The Joint Commission generally concurs with the process as outlined in this proposed CoP. The development, implementation, and comprehensive data driven program to monitor and evaluate performance including policies to address adverse events, will promote patient safety and quality driven processes. The Joint Commission accreditation standards, performance measures, and National Patient Safety Goals address the desired elements of a quality assessment and performance improvement system that are mapped out in this proposed rule. The elements that the Joint Commission views as essentials for the revised QAPI program are: electronic prescribing, clinical decision support, bar coding, adverse event reporting systems, and provider and patient education. Because

clinical decisions should be made on sound therapeutic choices and not on financial incentives or disincentives, clinical decision support is an essential element of any quality assurance system. The quality improvement system should be able to assess all licensed, independent practitioners' clinical decisions, as well as pharmacists' performance in adhering to the recommended clinical decision protocols. The Joint Commission also supports the use of bar codes. We encourage facilities that we accredit to adopt bar coding technology as a mechanism to avoid adverse medical events.

Sentinel Event Database

The Joint Commission is a strong supporter of reporting adverse events to help others learn from mistakes and near misses. To facilitate the reporting of such events, we advocate a non-punitive environment. The Joint Commission maintains a Sentinel Event database on all our accredited and certified organizations. After a sentinel event has occurred, the Joint Commission works with the organizations to conduct a root cause analysis. The root cause analysis helps the organization to identify systems that were in place that might have contributed to the sentinel event. The sentinel event database enables the Joint Commission to aggregate data in order to identify patterns and trends. When a pattern or trend is detected, the Joint Commission issues a *Sentinel Event Alert* that is transmitted in both hard copy and via the internet.

Recommendations for Performance Measures

The proposed rule references QAPI as a JCAHO requirement. However, the performance measure requirements identified in the proposed rule are vague. In the proposed rule, "areas to be evaluated" are suggested but not clearly defined. The current list of "areas to be evaluated" needs to be expanded upon. In present format, the areas are more like indicators rather than performance measures. One cannot assume that transplant centers will know what constitutes "objective" measures. The performance measure requirements need further clarification and definition in order to result in program improvement. The Joint Commission recommends that the QAPI programs prescribe "objective" measures including:

- Patient and donor selection criteria

- Accuracy of waitlist in accordance with OPTN waitlist
- Accuracy of donor and recipient matching
- Patient and donor management
- Techniques for organ recovery
- Consent practices
- Patient satisfaction
- Patient rights

HUMAN RESOURCES

Condition of Participation: Human Resources (Proposed Section §482.98)
This proposed rule outlines that transplant centers should ensure that all individuals who provide services are appropriately qualified. Joint Commission accreditation standards require that the organized medical staff oversees the quality of patient care, treatment, and services provided by practitioners privileged through the medical staff process. The rationale for this standard is that the organized medical staff is responsible for establishing and maintaining patient care standards and oversight of the quality of care, treatment, and services rendered by practitioners privileged through the medical staff process. The organized medical staff designates member licensed independent practitioners to provide oversight of care, treatment, and services rendered by practitioners privileged through the medical staff process. The organized medical staff recommends practitioners for privileges to perform medical histories and physical examinations; the governing body approves such privileges.

The Joint Commission strongly supports credentialing all health professionals involved in the delivery of care. Further, the Joint Commission believes that all providers should be subject to this condition of participation (e.g. clinical transplant coordinator certified by the American Board of Transplant Coordinators) including the surgeons who perform the transplants.

Joint Commission standards require that the organized medical staff has a credentialing process that is defined in the medical staff bylaws. Credentials review is the process of obtaining, verifying, and assessing the qualifications of an applicant to provide patient care, treatment, and services in or for a health care organization. The credentials review process is the basis for making appointments to membership of the medical staff; it also provides information for granting clinical privileges to licensed independent practitioners and other practitioners credentialed and privileged through the hospital's medical staff process.

The Joint Commission credentialing process includes a series of activities designed to collect relevant data that serve as the basis for decisions regarding appointment to membership on the medical staff, as well as the delineation of privileges recommended by the organized medical staff. Credentialing is the first step in the process that leads to privileging and that may lead to appointment to membership on the medical staff, if requested by the applicant.

The typical credentialing process includes processing applications, verifying credentials, evaluating applicant-specific information, and making recommendations to the governing body for appointment and privileges. The required information should include data on qualifications, such as licensure and training or experience. Although much of the specific information used to make decisions about privileges and appointment to membership is at the discretion of the organized medical staff, the range of information used should be explicit. The governance documents specify professional criteria for medical staff membership and clinical privileges. These criteria are designed to help establish an applicant's background, current competence, and physical and mental ability to discharge patient care responsibilities. Moreover, they are designed to help assure the medical staff and governing body that patients will receive quality care, treatment, and services.

The organized medical staff is also responsible for planning and implementing a privileging process. At the organization's discretion, the criteria for granting initial

privileges and renewing privileges may differ. The privileging process typically entails developing and approving a procedures list, processing the application, evaluating applicant-specific information and making recommendations to the governing body for applicant-specific delineated privileges, notifying the applicant and relevant personnel, and monitoring the use of privileges and quality of care issues.

The required information for credentialing should include data on the individual practitioner's performance that are collected and assessed on an ongoing basis. The organized medical staff defines the criteria for categories of medical staff membership. The categories and criteria include a category of membership that is responsible for the oversight of care, treatment, and services and requires the members in that category to have the requisite skills for oversight.

Organ Procurement (§482.100)

This proposed rule requires transplant centers to have a written agreement for receipt of organs. Joint Commission standards require transplant centers to have an explicit agreement that defines the specific responsibilities for the hospital and the OPO. "Elements of performance" that are assessed during an accreditation review include the following.

- The hospital has procedures, developed in collaboration with the designated OPO, for notifying the family of each potential donor of the option to donate—or decline to donate—organs, tissues, or eyes.
- This notification is made by an organ procurement representative or the hospital's designated requester.
- The hospital maintains records of potential donors whose names have been sent to the OPO and tissue and eye banks.
- The hospital works with the OPO and tissue and eye banks as follows:
  - In reviewing death records to improve identification of potential donors
  - To maintain potential donors while the necessary testing and placement of potential donated organs, tissues, and eyes takes place
  - In educating staff about donation issues

There are additional elements of performance for hospitals performing transplant services including:

- A hospital transplanting human organs must belong to the organ procurement and transplantation network (OPTN) established under section 372 of the Public Health Service Act and must abide by its rules.

42 CFR Part 488: Survey, Certification and Enforcement Procedures

Although CMS did not invite comments on the provisions contained in 42 CFR 488, the Joint Commission would like to take this opportunity to point out that the current process used to validate the Joint Commission's performance in evaluating hospitals compliance with the Medicare CoPs is seriously flawed. The Joint Commission acknowledges the need for continuing Federal oversight of approved accreditation organizations.

Once again, we commend CMS's hard work to codify the requirements for approval and re-approval of transplant centers. The Joint Commission stands ready to work with CMS to share Joint Commission's expertise. Our experience in accrediting and certifying various types of health care organizations, developing performance measurement metrics, convening experts and issuing National Patient Safety Goals provides valuable insights that can facilitate a smooth transition to the new CoPs for transplant centers.

Submitter : Mrs. Elaine Levy **Date:** 06/06/2005

Organization : UCSF Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachments:
First, is a Word document;
Second, is the same Word doc with signature as a pdf file.

CMS-3835-P-31-Attach-1.DOC

CMS-3835-P-31-Attach-2.PDF

Attachment #31
Indexing/Notes of CMS Proposed Conditions of Participation for Transplant Centers

Page	Content
1	Proposal for requirements for Transplant Center (TC) approval and 3-yr re-approval process
2	Comment submission process
6	Key statutory provisions
10	Current Mcare policy – kidney
13	Minimal service requirements (includes social worker, dietitian who counsels and monitors adherence, etc)
17-21	Current specified criteria for heart, liver and lung Vol criteria: heart & liver – 12 txs over 12 mos; lung – 10 tx over 12 mos intestinal – 10 txs over 12 mos
26	Reasons for new proposals – Conditions of Participations (CoP)
31	Provisions of the Proposed Regulations:
34	CoP- OPTN membership
37	CoP - Notification to CMS – new req re significant changes that would affect TCs approvals; (1) Change re "primary transplant surgeon" and "primary transplant physician" (2) Decrease in TC's vol or survival rates that could result in center being out of compliance
38	CoP – Ped Txs – If ped has same surgeons & QA as adults, reviewed as combined center but outcomes data reviewed separately; no min number of txs required for ped approval
42	CoP- Data Submission and Outcome Measurement for Initial Approval
45-48	Current OPTN – six forms
49	Current SRTR reports- 1 mo, 1yr, 3yr survivals for 2.5 yr base period, with 3yr survival based on earlier period than 1 mo and 1yr; SRTR uses Kaplan-Meier method – assumes failure rate for pts lost to follow-up same as pts with complete follow-up data; Modified Kaplan-Meier – pts lost to follow-up treated as dead on day after last ascertained survival (p60)
52	Expected pt survival rate – risk-adjusted statistic that provides an estimate of the fraction of pts expected to be alive at each reported time point based on nat experience for similar pts – uses Cox model
59	Proposed Data submission reqs

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Within 90 days of OPTN's due date, TC must submit at least 95% of required data including OPTN forms for tx candidate reg, tx recipient req, and recipient follow-up

60 Current 1 yr pt outcome req: heart –73%, liver-77%, lung - 69%, intestine – 65%
Compared to nat avg: heart - 86%, liver – 86%, lung- 78%

63 Proposed Outcomes for Heart, Kidney, Liver and Lung
Criteria of comparing TC's observed 1 yr pt survival and 1 yr graft survival to expected using data contained in most recent SRTR center-specific report.
Review adults and peds separately except for lungs.

67 Proposed Outcome Evaluation Methodology (To NOT Meet Criteria)
If observed rate is < expected, and all 3 of following tests are not met:
1) p-value of <0.05 to assure statistically certainty, 2) observed events minus expected events (O-E) >3, and # observed events divided by exp events >1.5

73 Minimum of 9 adult txs during 2.5 yr period, no ped min

90 New program can request approval using 1 month pt & survival data if human resources reqs are met, need follow-up data on at least 9 txs

91 Proposed Outcomes for Heart-lung, Intestine and Panc
NO outcome reqs since no risk-adjustment models exist due to low volume

99 Summary Chart for Data Submission & Outcome Measure Reqs for Initial Approval

100 CoP- Data Submission and Outcome Measurement for Re-Approval
Same as initial approval

106 Summary chart for Data Submission & Outcomes

112 Process Requirements – See Abecassis summary

1) Patient and living donor selection (p113)
2) Organ recovery and receipt (p117-119)
3) Patient and living donor management (p120-128); add to Abecassis – provide waitlist pts with update of waitlist status at least once a year (p125)
4) Quality assessment and performance improvement (QAPI) (p128-131)
5) Human resources (p131-135); add to Abecassis – provide multi-disciplinary team that includes nutrition and pharmacology ; also availability of expertise in medical specialties (p135)
6) Organ procurement (p135)
7) Patients' and living donors' rights (p136-149);
8) Additional reqs for kidney transplant centers (p150)

151 Special Procedures for Approval and Re-Approval of TCs
Introduces new rules for heart-lung and panc; changes process for reviewing applications for heart, intestine, kidney, liver and lung

154 Initial Approval Procedures – no formal application; letter signed by authorized rep, Mcare ID#, names of designated primary txp surgeon & designated primary txp physician, and statement from OPTN re compliance with all data submissions reqs.

Review procedures of SRTR data; outcome reqs for peds met separately from adults. Last review step is site visit. Approval effective as of date of approval letter. Three-yr limit to initial approval.

158 Re-Approval Procedures – CMS may evaluate compliance at any time, e.g., lack of data submissions. At least 180 days prior to end of 3 yr approval, data submission and outcome reqs reviewed; approval given if reqs met

160 Circumstances for approval without meeting data submission and outcome reqs

165 Effect of new CoPs on currently approved TCs – Within 180 days from regulations eff date, TCs submit letter requesting approval (one letter from hospital containing required information for all organs – p180); CMS/designee review data, then conduct survey. During review process, center continues to provide services.

183 Regulatory Impact Statement

213-248 Amendment to 42 CFR chapter IV

Submitter : **Dr. Christian Larsen** **Date: 06/06/2005**

Organization : **Emory Transplant Center, Emory University**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

The Emory Transplant Center leadership, the medical and surgical directors of our five transplant programs, and Emory University's Woodruff Health Science Center's leadership have reviewed the 'Medicare Program Hospital's Conditions for Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants' as published in the February 4, 2005 Federal Register. We applaud the efforts of the Centers for Medicare and Medicaid Services (CMS) to produce regulations for approval and re-approval of transplant programs that are based on sound, quality medical and transplant practices. We further appreciate that the underpinnings of the outcome measure methodologies and data submission requirements are those methods designed by and tested within the transplant community itself, the organ procurement and transplant network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR). However, while the process requirements are conceptually quite thorough, we are concerned that moving from theory to the clinical practice setting may prove to be a significant challenge. Thus, we have taken the opportunity afforded us by this comment period to respond to a few of the process conditions of participation (CoP).

The comments from the Emory Transplant Center leadership have been included in the issues section of the CMS ecomment form. Issues addressed include: Patient and Living Donor Selection, Patient and Living Donor Management, Quality Assessment and Performance Improvement, Human Resources, and Alternative Process to Re-approve Centers.

We appreciate the opportunity to respond to the proposed CMS regulations for approval and re-approval of transplant programs. We support the spirit of proposed regulations. These comments have been compiled as a consensus document endorsed by Emory Transplant Center leadership; the medical and surgical directors of Emory University Hospital's heart, kidney, liver and lung and pancreas transplant programs; and the Emory University Woodruff Health Sciences Center leadership.

Should you have any questions, feel free to contact me directly at 404.727.8466.

Sincerely,
Christian P. Larsen, M.D., D.Phil.
Carlos and Marguerite Mason Professor of Surgery
Director, Emory Transplant Center

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AHA Union of #32

EMORY UNIVERSITY SCHOOL OF MEDICINE

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June 1, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
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7500 Security Boulevard
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Re: CMS 3835-P

Dear Dr. McClellan:

The Emory Transplant Center leadership, the medical and surgical directors of our five transplant programs, and Emory University's Woodruff Health Science Center's leadership have reviewed the "Medicare Program Hospital's Conditions for Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants" as published in the February 4, 2005 *Federal Register.* We applaud the efforts of the Centers for Medicare and Medicaid Services (CMS) to produce regulations for approval and re-approval of transplant programs that are based on sound, quality medical and transplant practices. We further appreciate that the underpinnings of the outcome measure methodologies and data submission requirements are those methods designed by and tested within the transplant community itself, the organ procurement and transplant network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR). However, while the process requirements are conceptually quite thorough, we are concerned that moving from theory to the clinical practice setting may prove to be a significant challenge. Thus, we have taken the opportunity afforded us by this comment period to respond to a few of the process conditions of participation (CoP).

I. <u>CoP 482.90: PATIENT AND LIVING DONOR SELECTION and CoP 482.94: PATIENT AND LIVING DONOR MANAGMENT</u>

There is a concern that certain process requirements are so detailed that they may open transplant programs up to increased liability. An example is the patient selection standard that "before selected for transplant, [extra renal] programs must have employed or considered all other appropriate medical and surgical therapies that might be expected to yield both short and long-term survival comparable to transplantation."

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The Robert W. Woodruff Health Sciences Center

Who would define "all other appropriate medical and surgical therapies?" Are there national guidelines? Where are they housed? Lastly, how would others know that we "had considered all" such therapies?

An additional concern is the detail level of the documentation requirements in the patient's medical record throughout the transplant process. In CoP 482.90, documentation in the medical record upon listing must include "the patient selection criteria used." Once listed (CoP 482.94) it is proposed that documentation in the medical record include "that the patient is notified of a) his/her placement status at least yearly, even if no change in status...." Also when admitted for transplant, programs must "maintain written records of multidisciplinary patient care planning during pre-transplant period and multidisciplinary discharge planning post-transplant." This detailed level of oversight of the transplant process will 1) place additional resource burdens on the transplant programs, as well as 2) open the transplant program to ever-increasing liabilities. Thus, we have significant concerns with these process standards as proposed.

II. CoP 482.96: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT

Concerning the question of whether transplant programs could utilize existing staff from the hospital's QAPI department to meet this CoP of a data-driven QAPI and outcomes management program, it is our opinion that the comprehensive transplant QAPI program described in the *Federal Register* will require staff and resources beyond the existing hospital QAPI department to develop, implement, coordinate and monitor. While a single transplant program's QAPI initiatives might be supported by the hospital QAPI department, such would not be feasible to reflect the scope and complexity of large volume transplant centers with multiple transplant programs such as Emory's. Therefore, when considering this particular CoP for implementation, be advised that there will be additional expenses incurred by the transplant center for additional staff and resources to implement and maintain a comprehensive transplant QAPI and outcomes management program. Secondly, in our service area a proposed budget of $42,000 would not adequately cover projected expenses.

III. CoP 482.98: HUMAN RESOURCES

As a mature, experienced transplant center, we support certification of transplant coordinators. However, we are disturbed that a "qualified" clinical transplant coordinator has been narrowly defined by CMS as one who is certified by the American Board of Transplant Coordinators (ABTC). The Emory Transplant Center is comprised of five transplant programs with twenty-five transplant coordinators. Currently two of our coordinators within one transplant program have voluntarily elected to sit for and become ABTC certified. The remaining twenty-three, while not ABTC certified but ABTC qualified, perform the job functions listed in the *Federal Register*, conducting their duties in a quality manner, providing excellent care for those we serve.

As an academic tertiary healthcare system, we value our nursing staff and in this specific instance, our transplant nurse coordinators. As an institution, we encourage and facilitate continuing education and have developed a clinical and management levels program for nurses who meet specific continuing educational and practice requirements. To require certification of transplant coordinators, in addition to our own institutional merit levels, without at least a phased-in process could prove to be detrimental to our staff and expensive to implement and maintain institutionally.

In the midst of an ever-deepening nursing shortage, we ask that the requirement for certification be phased-in over time. Should the intent of this requirement be that only one coordinator per transplant program is certified, development of a fair and equitable certification program within the institution would also need a phase-in time period. We ask for clarification of the depth and scope of this CoP with consideration of a time period to phase-in the process.

IV. CoP 488.61: ALTERNATIVE PROCESS TO RE-APPROVE CENTERS

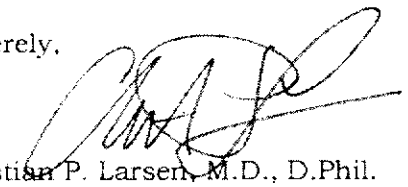
We agree that there should be a re-approval process to maintain the designation of a CMS approved transplant program. However the time frame of three years as well as the depth of the re-approval process is questionable. Regarding time frame, we assume that the proposed three years between approval and re-approval might have been adapted from the JCAHO model of accreditation. Recognizing that there are costs associated with preparation for any re-certification/re-accreditation process and with healthcare costs in general continuing to rise, we would propose a longer time between approval to re-approval perhaps four, five or even six years. Lengthening the time by even one year, from three to four years, would result in a 25% cost savings.

Desk reviews of outcome measures and data submission requirements prior to re-approval is appropriate whereas on-site compliance surveys should be focused on those centers which do not meet the outcome measures or data submission requirements as well as in those centers in which complaints have been lodged. A third flag for compliance surveys could include those centers in which information from the OPTN desk and on-site audit findings might indicate the appropriateness of a CMS compliance survey. However, we do not support the notion of compliance surveys of all programs with each re-approval submission process. This proposed alternative process would prove to be labor intensive and cost-prohibitive for both CMS and the transplant centers. Nor do we see the cost effectiveness of additional compliance surveys conducted on a random sampling of selected centers that have met outcome measures and data submission requirements.

In conclusion, we appreciate the opportunity to respond to the proposed CMS regulations for approval and re-approval of transplant programs. We support the spirit of proposed regulations. These comments have been compiled as a consensus document endorsed by Emory Transplant Center leadership; the medical and surgical directors of Emory University Hospital's heart, kidney, liver and lung and pancreas transplant programs; and the Emory University Woodruff Health Sciences Center leadership.

Should you have any questions, feel free to contact me directly at 404.727.8466.

Sincerely,



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